UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVSION

UNITED STATES OF AMERICA, *ex rel.* GREGORY M. GOODMAN,	)	Civil Case No.: 3:13-cv-00760
Plaintiff,	)	JUDGE TRAUGER
v.	)	**JURY TRIAL DEMAND**
ARRIVA MEDICAL, LLC, ALERE, INC, TED ALBIN and GRAPEVINE BILLING AND CONSULTING SERVICES, INC.,	)	
Defendants.	)	

UNITED STATES' AMENDED COMPLAINT-IN-INTERVENTION

Pursuant to the False Claims Act ("FCA"), 31 U.S.C. § 1379, *et seq.*, Plaintiff the United States of America ("United States") hereby submits this amended complaint-in-intervention against Defendants Arriva Medical, LLC ("Arriva"), Alere, Inc. ("Alere"), Ted Albin ("Albin"), and Grapevine Billing and Consulting Services, Inc. ("Grapevine") (collectively, "Defendants") and alleges as follows:

NATURE OF THE ACTION

1. Until December 2017 when it ceased business operations (a year after having its Medicare billing number revoked in November 2016), Arriva was a national mail-order supplier of diabetic testing supplies, primarily to Medicare beneficiaries. From November 2011 until October 2017, Arriva was wholly-owned and operated by Alere, both of which are now wholly-owned and controlled by non-party Abbott Laboratories ("Abbott"). During the period that it owned Arriva, Alere directed and controlled Arriva's business operations, including the conduct alleged herein. Since the early days of Arriva's existence in 2009, Ted Albin, through his company

Grapevine, has been a reimbursement consultant to Arriva and Alere, and, for a period, oversaw and directed Arriva's submission of claims to Medicare.

2. In a large-scale fraud scheme lasting from as early as 2009 until at least November 2016, Defendants, in violation of the Anti-kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), (1) knowingly and willfully paid kickbacks to Medicare beneficiaries in the form of (i) "free" or "no cost" home blood glucose monitors ("glucometers"), and (ii) the routine and systematic waiver of beneficiary copayment obligations, and then (2) submitted or caused to be submitted false claims to Medicare that were tainted by those unlawful kickbacks.

3. In an effort to induce Medicare beneficiaries to create and maintain customer relationships with Arriva and to purchase diabetic testing supplies from Arriva that were paid for by Medicare, Defendants implemented two interrelated kickback schemes.

4. The first scheme involved Arriva offering and providing Medicare beneficiaries with "free" or "no cost" glucometers. Under this scheme, Arriva marketed to Medicare beneficiaries "free" or "no cost" glucometers through its "no cost guarantee." Pursuant to the "no cost guarantee," Arriva promised that "[i]f Medicare denies a customer claim for any reason, we will not bill the customer for any reason." This meant that where Medicare denied a claim for a glucometer, Arriva would simply give the glucometer to the beneficiary for "free" or at "no cost."

5. By providing the glucometer for "free" or at "no cost," Arriva, ensured that most beneficiaries purchased diabetic testing supplies from Arriva on an ongoing basis.

6. This, however, did not always work, which led Defendants to implement the second interrelated kickback scheme.

7. Notwithstanding Arriva's "no cost guarantee," it was generally the case that Medicare beneficiaries owed copayment obligations when they received diabetic testing supplies

from Arriva. In some cases, Medicare paid for the glucometer, which created a 20 percent copayment obligation for the beneficiary. In virtually all cases, beneficiaries owed a 20 percent copayment on their ongoing testing supplies from Arriva, such as diabetic testing strips, lancets, spring-powered lancet devices ("lancet devices"), and calibrator solution/chips ("control solution").

8. Often, beneficiaries became Arriva customers on the promise of "free" or "no cost" glucometers, and later complained to Arriva about their copayment obligations. This created a threat that the beneficiaries would stop purchasing diabetic testing supplies from Arriva, and a risk that the ongoing revenue stream that was the entire purpose of the original kickback scheme would be diminished or eliminated.

9. In an effort to prevent Medicare beneficiaries from canceling their accounts and purchasing their diabetic supplies elsewhere, Arriva waived, wrote off, or simply failed to collect patient copayment obligations that were not paid for by secondary insurance.

10. At first, these waivers of copayment obligations came in the form of "courtesy adjustments" or other forms of individual waivers of copayment obligations that were authorized by, amongst others, Albin. Arriva's policy was simple. If a beneficiary complained about a copayment obligation or threatened to cancel his or her account, Arriva gave the beneficiary a "courtesy waiver" of the copayment obligation to "save the customer."

11. These waivers were routine. They occurred "every week," with the number of patients for whom such waivers were made increasing over time as Arriva's business expanded and it had more customers.

12. Then, periodically, as often as once a month, Arriva, under the direction and supervision of Albin and others, and with the knowledge and approval of Alere during the period

that Alere owned Arriva, engaged in "mass write-offs" of patient balances that included unpaid copayment obligations as well as the amounts for "free" or "no cost" meters that were paid as kickbacks to Medicare beneficiaries pursuant to Arriva's "no cost guarantee."

13. Over time, Defendants implemented a more systematic approach to the waiver of copayment obligations that was not limited to customers who complained about copayments. They simply made little to no effort to collect copayments from Medicare beneficiaries whose copayments were not covered by secondary insurance.

14. For years, Arriva did not send out invoices to Medicare beneficiaries seeking the payment of copayment obligations; and, when it finally did, it did so "irregularly." When it did send invoices, Arriva took little to no action to collect patient balances. Arriva did not call or send letters to Medicare beneficiaries seeking the payment of copayment obligations. Until at least 2015, Arriva had no collections department. Arriva did not cancel patients for failure to satisfy a copayment obligation — no matter how large the unpaid balance — unless that patient explicitly declared that he or she would never pay the copayment amount. Arriva did not utilize a collection agency to collect unpaid patient balances.

15. The effect of Arriva's non-existent collection efforts was that its collection rate for beneficiary copayment obligations was very low, at one point as low as 10 percent. This resulted in millions of dollars in waived Medicare beneficiary copayment obligations.

16. Additionally, under the supervision and approval of Alere, Arriva implemented policies pursuant to which copayment obligations could and would be waived and written off where (1) the beneficiary copayment obligation for a particular date-of-service was considered to be "small," or (2) three or fewer invoices had been sent to the beneficiary without payment.

17. Under the small balance copay waiver policy, if Arriva considered the copayment

obligation for a particular date-of-service to be "small," then the copayment obligation would be waived and written off without the beneficiary as much as being sent an invoice for the copayment.

18. Under the three invoice copay waiver policy, if a beneficiary simply failed to pay his or her copayment obligation for a particular date-of-service after receiving three invoices, that copayment obligation would be waived and written off as part of Arriva's periodic "mass write offs" of patient balances.

19. Because copayment obligations for individual orders of diabetic testing supplies can be quite small (although, they can become large when combined with copayment obligations for other orders), Defendants knew that by implementing the small copay waiver policy they were effectively eliminating the copayment on an on-going basis for a large number of Medicare beneficiaries who would, in many cases, never receive a copayment invoice from Arriva for any individual order because the small copayment obligations for each separate order would automatically and routinely be waived and written off by Arriva.

20. Similarly, given that Arriva (1) made almost no effort to collect patient balances, (2) marketed its products as being "free" or "no cost," and (3) did not cancel patients for failing to pay patient balances, Defendants knew that — where beneficiary copayment obligations were not already waived pursuant to the small balance waiver policy — Arriva's three invoice waiver policy would lead to the systematic and routine waiver of beneficiary copayment obligations.

21. The actual and intended effect of these policies and Defendants' conduct was that (1) Arriva routinely waived beneficiary copayment obligations, (2) beneficiaries were induced to continue to purchase diabetic supplies from Arriva, with many never or rarely having to pay any out-of-pocket expenses for those supplies, and (3) Medicare paid Arriva tens of millions of dollars (or more) in claims that were tainted by unlawful kickbacks.

22. Additionally, on behalf of Arriva, Defendants submitted or caused to be submitted scores of false claims to Medicare for new glucometers for beneficiaries Defendants knew had received a glucometer paid for by Medicare within the past five years, even though the new glucometers were for that reason not covered by Medicare. *See* 42 U.S.C. § 1395m(a)(7)(C)(ii); 42 C.F.R. § 414.210(f)(1).

23. Rather than making any effort to determine whether Medicare beneficiaries had received a glucometer paid for by Medicare in the past five years (or otherwise were not entitled to a meter paid for by Medicare), as a matter of policy and practice, Arriva provided all new customers with new glucometers, which were billed to Medicare without regard to whether the glucometers were covered by Medicare.

24. Finally, Arriva submitted or caused to be submitted false claims to Medicare for items that were purportedly provided to 211 beneficiaries who had been deceased for more than fourteen days as of the dates of service for the claims. In November 2016, Arriva's Medicare billing number was revoked because of this misconduct.

THE PARTIES

25. The United States bring this action on behalf of the Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid Services ("CMS"), the administrators of the Medicare program.

26. Relator Gregory M. Goodman ("Relator") is a resident of Tennessee. Relator is a former sales representative at Arriva. He worked for Arriva out of its Antioch, Tennessee call center from February 2013 to November 2013, during a period when Arriva was owned by Alere. Relator filed his original *qui tam* complaint in this action on August 1, 2013 against Arriva and Alere.

27. Defendant Arriva is a Florida limited liability company with headquarters in Coral Springs, Florida. Until it ceased business operations in December 2017, Arriva was a national mail-order supplier of diabetic testing supplies, including glucometers, testing strips, and lancets. It sold and mailed diabetic supplies (and other products) to customers across the country, including customers who resided in the Middle District of Tennessee.

28. From 2012 through at least November 2013, Arriva operated a call center in Antioch, Tennessee, through which it solicited customers and processed orders for diabetic supplies for Medicare beneficiaries throughout the United States.

29. In November 2016, CMS revoked Arriva's Medicare billing number after CMS found that Arriva billed Medicare for services purportedly provided to Medicare beneficiaries who were deceased on the purported dates-of-service. In December 2017, Arriva ceased business operations. Arriva continues to exist as a corporate entity.

30. Defendant Alere is a Delaware corporation with its principal place of business in Waltham, Massachusetts. Alere purchased Arriva in November 2011 for approximately $65 million. From November 2011 to October 2017, Arriva was owned, operated, and managed by Alere.

31. In October 2017, Abbott completed its purchase of Alere (which included Arriva). Abbott originally agreed to purchase Alere in February 2016 for $5.8 billion. In December 2016, Abbott filed suit against Alere seeking to undo the deal in part because of government investigations of Alere and the revocation of Arriva's Medicare billing number. In April 2017, Abbott and Alere settled that lawsuit and Abbott agreed to purchase Alere for $5.3 billion, $500 million less than then the original purchase price. By virtue of Abbott's purchase of Alere, Arriva is currently owned and controlled by Abbott. In November 2017, a year after CMS revoked

Arriva's Medicare billing number, Abbott made the decision to cease Arriva's business operations as of December 31, 2017.

32. Defendant Ted Albin is a resident of Florida. Defendant Grapevine is a Florida corporation with its principal place of business in Royal Palm Beach, Florida. At all relevant times, Albin was an employee of Grapevine. Grapevine is wholly-owned and controlled by Albin. Through Grapevine, Albin is currently a consultant with Abbott, a position he has held since January 2018. Albin's current responsibilities include responding to overpayment demands or requests for additional information that CMS may make to Arriva in connection with claims Arriva submitted to Medicare.

33. From 2009 until December 2017, through Grapevine, Albin was a consultant for Arriva and Alere. For years, Albin oversaw Arriva's efforts to seek reimbursement from Medicare for diabetic testing supplies sold to beneficiaries of Medicare, including submitting claims to Medicare on Arriva's behalf. Albin also oversaw Arriva's process for writing off the cost of "free" or "no cost" glucometers and copayment waivers.

JURISDICTION & VENUE

34. This court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1345 because this action is brought by the United States as a plaintiff pursuant to the FCA.

35. This court has personal jurisdiction over Defendants. *See* 31 U.S.C. § 3732(a). Defendants can be found in and/or have transacted business in the Middle District of Tennessee. Additionally, a substantial portion of the events that give rise to the claims alleged herein occurred in this jurisdiction.

36. Similarly, venue is proper in this jurisdiction under 31 U.S.C. § 3732(a) and 28

U.S.C. §§ 1391(b) and 1395(a). Defendants can be found in and/or have transacted business in the Middle District of Tennessee. Additionally, a substantial portion of the events that give rise to the claims alleged herein occurred in this jurisdiction.

37. From at least 2012 through November 2013, Arriva and Alere operated a call center in Antioch, Tennessee, which is located in the Middle District of Tennessee. Through this call center, Arriva and Alere communicated with Medicare beneficiaries and processed purchase orders for diabetic testing supplies and other items, many of which were tainted by the kickbacks alleged in this complaint, and for which claims for payment were later made to Medicare. Additionally, from as early as 2010 until December 2017, Arriva sold and shipped diabetic testing supplies and other items to Medicare beneficiaries who resided in this jurisdiction. Alere, a large medical device company, also regularly sells medical devices and other items to customers who reside in this jurisdiction.

38. Through his position as a consultant to Arriva and Alere, Albin directly and indirectly communicated with and provided direction to Arriva employees who worked at Arriva's Antioch call center about whether they could agree to provide beneficiaries free glucometers or waive copayment obligations. Albin also consulted with Arriva with respect to the transaction that led to Arriva's acquisition of the call center. As part of that effort, Albin travelled to Antioch and participated in interviews of the employees who worked at the call center to determine who would be retained. Albin's actions were all taken as an employee and owner of Grapevine.

39. Additionally, from as early as 2010 until at least 2016, defendants caused thousands (and likely hundreds of thousands) of claims for diabetic testing supplies to be submitted to Medicare in this jurisdiction. CGS Administrators, LLC ("CGS"), which is a Medicare contractor that processes claims for durable medical equipment (including diabetic testing supplies), is

located in Nashville, Tennessee. Defendants caused many of the false claims at issue in this action (totaling in the millions) to be submitted to CGS in this jurisdiction.

LEGAL FRAMEWORK

The False Claims Act

40. Under the FCA, any "person" who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent; [or]
>
> (C) conspires to commit a violation of subparagraph (A) [or] (B) ….
>
> is liable to the United States Government [for statutory damages and such penalties as are allowed by law]."

31 U.S.C. §§ 3729(a)(1)(A)-(C).

41. "Claim" is defined in the FCA "as any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that— (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government— (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(b)(2).

42. The FCA provides that "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

43. The FCA further provides that "knowing" and "knowingly":

> (A) means that a person, with respect to information
>
> i. has actual knowledge of the information;

ii. acts in deliberate ignorance of the truth or falsity of the information; or

iii. acts in reckless disregard of the truth or falsity of the information; and

(B) requires no proof of specific intent to defraud.

31 U.S.C. § 3729(b)(1).

44. Under the FCA, any person who is found to have violated the FCA "is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . . plus 3 times the amount of damages which the Government sustains because of the act of that person." 31 U.S.C. §§ 3729(a)(1).

45. The current level of civil penalties for violations of the FCA that are assessed after January 29, 2018 is not less than $11,181 and not more than $22,363. *See* 28 C.F.R. § 85.5. These penalties are subject to further adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990.

46. The FCA further provides that "[a] person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages." 31 U.S.C. § 3729(a)(3).

The Medicare Program, the Five Year Rule, and Copayment Obligations

47. In 1965, Congress enacted Title XVIII of the Social Security Act, which established the Medicare Program to provide health insurance for the elderly and disabled.

48. Payments from the Medicare Program come from a trust fund known as the Medicare Trust Fund. The Medicare Trust Fund is funded in part through contributions from the federal government. Medicare is a federal health care program.

49. Medicare has four parts: Part A (Hospital Insurance); Part B (Medical Insurance); Part C (Managed Care Plans); and the Part D (Prescription Drug Program).

50. This case involves claims submitted to Medicare Part B. Medicare Part B covers services and items.

51. Amongst the types of items covered by Medicare Part B is durable medical equipment ("DME").

52. DME is "equipment, furnished by a supplier or a home health agency that meets the following conditions: (1) Can withstand repeated use. (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years. (3) Is primarily and customarily used to serve a medical purpose. (4) Generally is not useful to an individual in the absence of an illness or injury. (5) Is appropriate for use in the home." 42 C.F.R. § 414.202.

53. To obtain reimbursement for certain DME, suppliers submit a form known as the CMS 1500, or its electronic equivalent known as the 837P. *See* 42 C.F.R. § 424.32.

54. Among the information the supplier includes on these forms are certain five-digit codes, including Healthcare Common Procedure Coding System ("HCPCS") codes, that identify the supply or product provided to Medicare beneficiaries and for which reimbursement is sought, and the unique billing identification number of the supplier. CMS assigns reimbursement amounts to HCPCS codes.

55. Medicare suppliers that seek reimbursement for a home glucometer are required to use the HCPCS code E0607 on Medicare claims forms to obtain payment.

56. Medicare suppliers that seek reimbursement for a box of blood glucose test or reagent strips ("strips") are required to use the HCPCS code A4253 on Medicare claims forms to obtain payment.

57. Medicare suppliers that seek reimbursement for control solution (which is used for diabetic testing) are required to use the HCPCS code A4256 on Medicare claims forms to obtain

payment.

58. Medicare suppliers that seek reimbursement for a lancet device are required to use the HCPCS code A4258 on Medicare claims forms to obtain payment.

59. Medicare suppliers that seek reimbursement for a box of lancets are required to use the HCPCS code A4259 on Medicare claims forms to obtain payment.

60. Both the CMS 1500 and the 837B include an express certification from the supplier that the claim is "accurate, complete, and truthful."

61. The 837B also includes an acknowledgment "that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to this Agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law."

62. The CMS 1500 includes an express certification from the supplier that "the claim, whether submitted by me or on my behalf by a designated billing company, complies with all applicable Medicare and/or Medicaid law, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute."

63. The CMS 1500 also includes a certification that the party submitting the form has (1) "familiarized [itself] with all applicable laws, regulations, and program instructions," and (2) "provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision."

64. As dictated by statute, Medicare only pays for replacement of durable medical equipment after the reasonable useful lifetime of these items has been reached or if the item has been lost or irreparably damaged. 42 U.S.C. § 1395m(a)(7)(C)(ii). DME that is meant to replace DME that has not reached its useful lifetime is thus excluded from coverage.

65. CMS has determined that the reasonable durable lifetime of all DME is no less than 5 years. 42 U.S.C. § 1395m(a)(7)(C)(iii) ("The reasonable useful lifetime of an item of durable medical equipment under this subparagraph shall be equal to 5 years" unless the HHS Secretary has determined otherwise.); 42 C.F.R. § 414.210(f)(1) ("carriers may determine the reasonable useful lifetime of equipment but in no case can it be less than 5 years"). For purposes of this Complaint, this will be referred to as the "Five Year Rule."

66. As a general matter, Medicare will not pay for any expense that is "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). This is a separate statutory requirement from the Five Year Rule.

67. When Medicare or its contractors deny payment for supplies due to the Five Year Rule, they frequently use denial code 151 – which stands for "[p]ayment adjusted because the payer deems the information submitted does not support this many/frequency of services." Medicare or its contractors also uses denial code 150 – which stands for "Payer deems the information submitted does not support this level of service."

68. As a general matter, Medicare covers 80 percent of the reasonable cost of medical services, with the remaining 20 percent being owed by the beneficiary as a copayment obligation. *See, e.g.*, 42 U.S.C. § 1395m(a); 42 C.F.R. § 414.210(a); *see also* OIG Special Fraud Alert, 59 Fed. Reg. 65372-01 (Dec. 19, 1994) ("Copayment . . . is the portion of the cost of an item or service which the Medicare beneficiary must pay. Currently, the Medicare Part B coinsurance is generally 20 percent of the reasonable charge for the item or service.").

69. Thus, except in rare circumstances, providers are required to collect the full 20 percent copayment from Medicare beneficiaries or their secondary insurers. Moreover, as is made

clear in the Medicare Claims Processing Manual, a "reasonable collection effort" must be made to collect the copayment, which requires, at minimum, "a genuine, rather than token, collection effort." MEDICARE CLAIMS PROCESSING MANUAL, Chapter 23, § 80.8.1.

The Federal Anti-Kickback Statute

70. Under the AKS, "whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce that person . . . to purchase . . . any item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony. . . ." 42 U.S.C. § 1320a-7b(b)(2).

71. "A person need not have actual knowledge of [the AKS] or specific intent to commit a violation" of the AKS to be found to have violated the statute. 42 U.S.C. § 1320a-7b(h).

72. As a matter of law, "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim" under the FCA. 42 U.S.C. § 1320a-7b(g).

73. The AKS prohibits offering or paying remuneration to Medicare beneficiaries to induce the purchase of items that will be paid in whole or in part by Medicare.

74. The offer or provision of "free" or "no cost" glucometers to Medicare beneficiaries constitutes the payment of "remuneration" under the AKS.

75. Similarly, the waiver, forgiveness, or failure to collect Medicare copayments constitutes the payment of "remuneration" under the AKS.

76. Consequently, it is a violation of the AKS, and thus the FCA, for a party to knowingly and willfully offer or provide "free" or "no cost" DME to a Medicare beneficiary to induce that person to purchase any item that will be paid in whole or in part by Medicare.

77. Additionally, it is a violation of the AKS, and thus the FCA, for a party to knowingly and willfully routinely waive or fail to collect Medicare copayments to induce a Medicare beneficiary to purchase any item that will be paid in whole or in part by Medicare.

78. The Officer of the Inspector General for HHS ("HHS-OIG") has issued fraud alerts with respect to the waiver of copayment obligations for beneficiaries of federal health care programs.

79. The first fraud alert on this topic was issued almost twenty-five years ago in 1994. In that document, HHS-OIG declared that the "[r]outine waiver of deductibles and copayments . . . is unlawful because it results in (1) false claims, (2) violations of the anti-kickback statute, and (3) excessive utilization of items and services paid for by Medicare." OIG Special fraud alert, 59 Fed. Reg. 65372-01 (Dec. 19, 1994).

80. This is because a "provider, practitioner, or supplier who routinely waives Medicare copayments or deductibles is misstating [to CMS the] actual charge" of the item. OIG Special fraud alert, 59 Fed. Reg. 65372-01 (Dec. 19, 1994). By way of example, "if a supplier claims that its charge for a piece of equipment is $100, but routinely waives the copayment, the actual charge is $80." *Id.* "As a result of the supplier's misrepresentation, the Medicare program is paying . . . more than it should for this item."

81. Relying on OIG's guidance on this issue, CMS's Medicare Claims Processing Manual explains that:

> Deductible and coinsurance amounts are taken into account (included) in determining the reasonable charge for a service or item. In this regard, a billed amount that is not reasonably related to an expectation of payment is not considered the "actual" charge for the purpose of processing a claim or for the purpose of determining customary charges.
>
> MEDICARE CLAIMS PROCESSING MANUAL, Chapter 23, § 80.8.1.

82. In the 1994 fraud alert, HHS-OIG provided a non-exhaustive list of indicators of

improper copayment waivers, including:

- Advertisements which state: "Medicare Accepted As Payment in Full," "Insurance Accepted As Payment in Full," or "No Out-Of- Pocket Expense." Advertisements which promise that "discounts" will be given to Medicare beneficiaries.

- Routine use of "Financial hardship" forms which state that the beneficiary is unable to pay the coinsurance/deductible (i.e., there is no good faith attempt to determine the beneficiary's actual financial condition).

- Collection of copayments and deductibles only where the beneficiary has Medicare supplemental insurance ("Medigap") coverage (i.e., the items or services are "free" to the beneficiary).

- Charges to Medicare beneficiaries which are higher than those made to other persons for similar services and items (the higher charges offset the waiver of coinsurance.)

- Failure to collect copayments or deductibles for a specific group of Medicare patients for reasons unrelated to indigency (e.g., a supplier waives coinsurance or deductible for all patients from a particular hospital, in order to get referrals).

- "Insurance programs" which cover copayments or deductibles only for items or services provided by the entity offering the insurance.

- The "insurance premium" paid by the beneficiary is insignificant and can be as low as $1 a month or even $1 a year. These premiums are not based upon actuarial risks, but instead are a sham used to disguise the routine waiver of copayments and deductibles.

OIG Special Fraud Alert, 59 Fed. Reg. 65372-01 (Dec. 19, 1994).

83. In a 2014 fraud alert, HHS-OIG reiterated its "longstanding" position that "[p]roviders and suppliers that routinely waive cost-sharing amounts . . . may be held liable under the anti-kickback statute." 79 Fed. Reg. 59717, 59720 (Oct. 3, 2014). This is because "[s]uch waivers may constitute prohibited remuneration to induce referrals under the anti-kickback statute . . . ." *Id.*

84. HHS-OIG has recognized a limited "exception to the prohibition against waiving copayments." OIG Special Fraud Alert, 59 Fed. Reg. 65372-01 (Dec. 19, 1994). Under this limited exception, "suppliers may forgive the copayment in consideration of a particular patient's financial

hardship." *Id.*

85. However, HHS-OIG has emphasized that (1) "this hardship exception . . . must not be used routinely; it should be used occasionally to address the specific financial need of a particular patient," and (2) "a good faith effort to collect . . . copayments must be made." *Id.* OIG Special Fraud Alert, 59 Fed. Reg. 65372-01 (Dec. 19, 1994).

FACTUAL ALLEGATIONS

I. Background

A. Arriva's Corporate History and Alere's Ownership and Control of Arriva

86. Arriva was founded in 2009 by David Wallace and Timothy "Tim" Stocksdale, who, along with other investors, owned Arriva until November 2011, when Alere bought Arriva.

87. Wallace and Stocksdale had previously owned a different supplier of diabetic testing supplies called Access Diabetic Supply, and, thus, were experienced in the business of diabetic testing supplies.

88. From Arriva's founding in 2009, until its sale to Alere in 2011, Wallace and Stocksdale jointly operated and managed Arriva.

89. From November 2011 until the sale of Alere and Arriva to Abbott in October 2017, Alere and its executives operated and managed Arriva.

90. From November 2011 until at least August 2013, after the sale of Arriva to Alere, Wallace and Stocksdale continued to work as executives at Arriva pursuant to separate employment contracts with Arriva. Wallace had the title of "President," and Stocksdale had the title of "Senior Vice President."

91. Pursuant to the terms of their employment contracts, Stocksdale and Wallace worked under the supervision of Alere. Wallace's employment contract specifically stated that,

as the "President" of Arriva, Wallace was "subject to the supervision and direction of the head of Alere's Diabetes SBU, and until such time as that role is filled, Alere's President and CEO, Ron Zwanziger." Stocksdale worked under the supervision of Wallace, and, thus, in effect, Alere.

92. Moreover, according to Wallace, after the sale of Arriva to Alere, "Alere completely took over the company . . . any kind of marketing and finance, all those decisions were really being driven by Alere."

93. Subsequent presidents of Arriva also worked under the supervision and direction of Alere and its executives. For example, William "Chip" Stocksdale (the brother of Tim Stocksdale), who was the president of Arriva from 2013 to 2015, was promoted and hired to that position by Ron Zwanziger, the founder and CEO of Alere.

94. Chip Stocksdale initially reported to and was supervised by Zwanziger. Later, he reported to and was supervised by Daniella Cramp, as well as Jon Russell and Claudio Araujo, all executives at Alere who were responsible for oversight of Arriva.

95. According to Tim Stocksdale, "in the Alere organization structure, Daniella Cramp made all of the ultimate decisions. She was, effectively, the CEO . . . all major decisions went through her."

96. In 2016, Araujo, while still retaining his position at Alere, became the president of Arriva. Araujo received paychecks from both Arriva and Alere. Araujo was president of Arriva until December 2017.

97. Alere took numerous actions to exert control over Arriva and the management of Arriva's operations.

98. For example, Alere executives held quarterly meetings with Arriva executives to discuss and direct the management of Arriva's business. At these meetings, Arriva executives

made presentations to Alere executives, such as Cramp or Araujo, on the operations of Arriva's business. These and other Alere executives gave directions as to actions to be taken by Arriva.

99. Alere executives, including Cramp, Araujo, and Russell routinely reviewed Arriva's financial records, and directed actions that Arriva should take to promote revenue and profitably growth.

100. Arriva also prepared an "Executive Report," which included detailed financial and operational information about Arriva's business, and that was regularly provided to Alere management, including Cramp, Araujo, and Russell. These Executive Reports and other financial documents included information regarding Arriva's write offs for glucometers and copayment obligations, which were often referred to as "bad debt."

101. Alere ran Arriva's compliance function. Arriva's head of compliance, Ryan Wettergren, was an Alere employee with the title Associate Director of Global Compliance for Alere.

102. Arriva was also subject to audits by Alere. For example, from May 11, 2015 to May 22, 2015, a team led by Alere's Vice President for Global Audit ran an audit of Arriva's business functions, which resulted in an audit report sent to Cramp and Araujo in June 2015.

103. In advertisements and other materials, Arriva marketed itself as an "Alere Company."

104. Arriva customer service representatives identified themselves to actual and potential customers as representatives of "Arriva Medical, an Alere Company."

105. At least one Arriva employee has indicated that he understood that functionally "we are all part of Alere." That executive, Robert Emerson, ultimately held positions at both Arriva and Alere Home Monitoring (an Alere business unit which oversaw Arriva), both as the director

of reimbursement.

106. Arriva also transferred much of its profits to Alere, including through loans from Arriva to Alere. In fact, as of Arriva's cessation of business in December 2017, Alere owed Arriva between $80 million and $100 million pursuant to inter-company loans made by Arriva to Alere. At other times, that amount was as high as $150 million or more.

107. Upon the sale of Alere and Arriva to Abbott, Abbott took control of the operations and management of Arriva. Abbott ceased Arriva's operations in the face of CMS having revoked Arriva's billing number. Abbott also made the decision to retain Albin to act as a consultant for Arriva. Abbott currently directs Arriva's efforts to seek reimbursement for Medicare claims that Arriva has submitted, but which have been denied or otherwise not paid by CMS because Arriva's billing number was revoked.

108. Additionally, in early 2018, Abbott hired Emerson to work for Abbott Rapid Diagnostics, which now includes Alere Home Monitoring as one of its divisions.

B. Arriva's Diabetic Testing Supply Business

109. Arriva's primary business was that of a national mail-order supplier of diabetic testing supplies. It also sold ancillary products, such as wrist, back, and knee braces. For a period, Arriva also ran a pharmacy.

110. For most of Arriva's existence, approximately 90 percent of its customers were Medicare beneficiaries.

111. According to Tim Stocksdale, one of Arriva's original co-owners, "the intention was to focus strictly on the Medicare patient base. . . . So, we had set up our advertising, our intake scripts, everything to focus very – like a laser on the Medicare populations."

112. At its height, Arriva had more than 800,000 customers who purchased diabetic

testing supplies.

113. This was a profitable business for Arriva. In 2015 alone, Arriva generated over $80 million in net revenues from the sale of glucometers and other diabetic testing supplies. From 2012 through October 2017, the profits from Arriva's diabetic testing supply business flowed solely and fully to Arriva's parent Alere.

114. Diabetic testing supplies primarily include glucometers, testing strips, and lancets.

115. Together, these items are used by persons with diabetes to monitor blood sugar levels. A lancet is used by the patient to draw blood, which is then placed on a testing strip, which, in turn, is inserted into a glucometer, which is a small machine that measures the blood sugar level of the patient.

116. Depending on the determination of medical necessity by a physician, a diabetic patient may be required to test his or her blood sugar levels infrequently (*e.g.* once a week) or very frequently (*e.g.* numerous times a day). The amount of testing directed by the doctor is set out in the prescription.

117. Diabetes is a chronic disease. Thus, in most cases, a diabetic patient will be required to test for indefinite, and typically long, periods of time.

118. If certain conditions are satisfied, including medical necessity and a doctor's prescription, diabetic testing supplies are covered by Medicare Part B.

119. Lancets and strips are typically used once (or in the case of lancets potentially a few times) and discarded.

120. Glucometers, on the other hand, are designed to be used over and over again. Thus, glucometers qualify as DME under 42 C.F.R. § 414.202, and are subject to the Five Year Rule.

121. Diabetic testing supplies are widely available and, for most people, easy to

purchase. They can be purchased at any local pharmacy, as well as national retailers. They can also be purchased online.

122. There are dozens of manufacturers of diabetic testing supplies, which produce glucometers of various stripes and functionality. At base, virtually any glucometer will perform the basic function of measuring glucose levels in the patient's bloodstream.

123. The decision to purchase one glucometer over another is largely a matter of patient preference. For example, some glucometers may have large screens that make it easier to read the results. Other glucometers may be more compact and better suited for travel.

124. Testing strips are typically tied to a particular brand of glucometer. Thus, the testing strips used for glucometer A usually cannot be used for glucometer B.

125. Consequently, once a patient purchases a particular glucometer, he or she must purchase the particular strips designed for that brand of glucometer. The patient will not be able to purchase strips from another brand or manufacturer. Those strips will not work in the glucometer that was purchased.

126. The effect of this is that the bulk of the profits in the diabetic testing supply business are not in the sale of the glucometer. They are in the sale of the strips.

127. As Tim Stocksdale put it: "Test strips make up the vast majority of the revenue and profit."

128. Although the cost of a glucometer is significant (Medicare's reimbursement for glucometers has exceeded $70), this is a one time payment.

129. The strips on the other hand must be purchased on an ongoing basis. And, depending on the direction of a physician regarding the number of times the patient needs to test his or her blood glucose levels per day, a patient may use (and discard) numerous strips a day.

Over time (potentially a short period of time), the amount spent on strips far exceeds the amount spent on the glucometer.

130. Because a patient can only use the brand of testing strips associated with the glucometer purchased, the sale of a glucometer to a particular patient creates an ongoing revenue stream for the strips sold to that patient.

131. Tim Stocksdale has described this as the "razor and razor blade business type of business model." As Stocksdale explained in the context of a manufacturer, "[t]hey would want people to get one of their meters because only their test strips would work in the meter that they distributed. Just like Gillette would want people to get a razor so they can sell their razor blades."

132. As Stocksdale further explained: "They would not supply the meters unless you were buying the test strips. So it was a combination . . . [T]heir interest was selling test strips."

133. This principle applies equally as well to a supplier, particularly if the supplier has exclusive or near-exclusive rights to sell a particular brand of glucometer and associated diabetic testing supplies. If the supplier can induce a patient to purchase a particular brand of glucometer that it supplies, then it can create an ongoing revenue stream for the sale of strips that are unique to that glucometer.

134. The supplier can create and maintain this revenue and profit stream even where the patient could conceivably purchase the strips from another supplier. In the case of a mail-order supplier, the supplier will typically reach out to the patient on a periodic basis to offer to send the patient additional testing strips and lancets without the patient having to do anything more than confirm that additional strips and lancets are needed. Thus, where the ongoing sale of strips and lancets is performed on virtual autopilot, the supplier creates an ongoing stream of revenue and profit for strips and lancets simply by creating a customer relationship. This relationship is

particularly lucrative if the cost of the items are covered by insurance, like Medicare.

135. Arriva's financial records reflect this reality. For example, in 2015, Arriva generated approximately $78.5 million in net revenue for the sale of testing strips and lancets. In contrast, in that same period, Arriva generated approximately $2.5 million in net revenue from the sale of glucometers. This is a ratio of 31 to 1.

136. Accordingly, the key to the diabetic testing supply business model is to induce the patient to obtain and use the glucometer that the supplier sells. Once that occurs, in most cases, the ongoing revenues and profits from the sale of the strips and lancets will be captured by the supplier for as long as the patient uses the glucometer.

137. As described in detail below, Arriva's strategy for inducing patients to purchase diabetic testing supplies from Arriva to create this ongoing stream of revenue and profitability was to offer and pay kickbacks to Medicare beneficiaries in the form of (1) "free" or "no cost" glucometers and (2) the waiver or forgiveness of copayment obligations for those meters, as well as for strips and lancets.

II. Defendants Submitted or Caused to be Submitted False Claims to Medicare that Were Tainted by Unlawful Kickbacks

138. Defendants implemented two interrelated kickback schemes to induce Medicare beneficiaries to create and maintain customer relationships with Arriva that created long-term revenue and profit streams to Defendants for the provision of diabetic testing supplies that were paid for by Medicare.

139. The first scheme involved Arriva offering and providing Medicare beneficiaries with "free" or "no cost" glucometers to induce the beneficiaries to purchase diabetic testing supplies from Arriva.

140. The second scheme involved Arriva routinely waiving Medicare beneficiaries'

copayment obligations to induce those beneficiaries to continue to purchase diabetic testing supplies from Arriva.

A. Kickback Scheme #1: "Free" or "No Cost" Meters

141. Defendants offered and paid kickbacks to Medicare beneficiaries in the form of "free" or "no cost" glucometers.

142. Starting as early as its first year of existence in 2009, and continuing until at least 2015 and likely later, Arriva implemented what it called a "no cost guarantee" to induce prospective customers — particularly Medicare beneficiaries — to purchase diabetic testing supplies from Arriva.

143. This policy was first approved by Arriva's senior leadership, including Wallace and Stocksdale, and was allowed to continue in existence by Alere in the period after Alere's acquisition of Arriva.

144. In a document titled "NO COST METERS" that was circulated to Arriva's sales team in September 2009, sales representatives were informed of "The Arriva NO COST Guarantee for blood glucose meters." As the document explained: "We offer our customers a NO COST GUARANTEE for new meters. If Medicare denies a customer claim for any reason, we will not bill the customer for any reason."

145. The document further indicated that the "no cost guarantee" was applicable to other items sold by Arriva, including other diabetic testing supplies like "strips, lancets, lancing device[s], control solution, and batteries."

146. The document further instructed sales representatives on how to respond to inquiries about whether the glucometers were free. It provided the following:

Prospect question:
Is the meter free?

Arriva response:

Arriva offers a no cost guarantee!

147. Arriva's "no cost guarantee" was meant to communicate to beneficiaries that the items were free. As Tim Stocksdale, one of Arriva's original co-owners, explained: "this 'no cost' language . . . was an alternative to free."

148. Arriva marketed its "no cost guarantee" to Medicare beneficiaries, often telling them that the glucometers were "free."

149. For example, in a television advertisement, versions of which ran from 2010 until at least 2015 and likely later, Arriva told prospective customers: "Call now and Arriva Medical will send you one of these meters . . . for FREE."

150. Similarly in a radio advertisement that was created in 2010, the pitch from Arriva was "Call now and Arriva Medical will send you one of these new meters for free."

151. Arriva had an advertising budget of as much as $10 million a year. And, internal Arriva documents show that Arriva greatly outspent rivals on advertising, particularly television advertising.

152. Arriva reinforced the message that the glucometers and other diabetic testing supplies were "free" or "no cost" in direct interactions between Medicare beneficiaries and Arriva sales representatives.

153. In a "rebuttal sheet" that was circulated to Arriva sales representatives in August 2010, Arriva trained sales representatives to respond to the customer objection that "I thought this was all free" with the response "Yes, our meters are sent at no cost to you."

154. Similarly, in a 2012 script that Arriva required sales representatives to read to customers during phone calls said: "I want to let you know that since you have Medicare, you have the option to purchase or rent a meter, but we will be sending you a meter at no charge."

155. The script was the same in 2013, when Arriva operated a call center in Antioch. Arriva distributed "Standard Close Deal Notes" to its sales team in January 2013 that provided:

> Objection – Is the meter free?
>
> Response
> The meter comes to you with a "no cost guarantee." If your insurance denies the claim for any reason, we will not send you a bill for the meter.

156. In a "Welcome Kit" that came with a beneficiary's first order of diabetic testing supplies, Arriva again reinforced the theme that the diabetic testing supplies came at "NO Cost" to the beneficiary. As the document explained it, "Medicare . . . will pay for your diabetic supplies."

157. In addition to using the promise of "free" or "no cost" glucometers to induce new customers to purchase diabetic testing supplies from Arriva, Arriva used similar promises to induce current customers who had not recently ordered supplies to purchase diabetic testing supplies again.

158. For example, an August 2011 email to Arriva's reorder and customer service teams from Arriva's head of marketing stated the following:

> Last week and this week we sent a "GET AN EXTRA METER AT NO COST" mailing to our active customers that have not ordered since October 1st, 2010. This offer is available to customers that have NOT ordered since October 1st, 2010.
>
> The goal is to get some of our older customers who have not placed an order in over 10 months to order again . . . .

159. Around the same time in July 2011, Arriva sent a flyer to customers who "were past due for . . . diabetic supplies" offering a "FREE back-up meter" if "you order your supplies before August 31th, 2011."

160. Similarly, in May 2012, Arriva's head of marketing sent an email to sales and customer representatives regarding Arriva's strategy for inducing "Medicare primary customers"

who had recently cancelled to "reorder from Arriva." Arriva's strategy was to offer a free "Meter Upgrade."

161. Arriva understood that these advertisements led beneficiaries to believe that the glucometers were free.

162. For example, a December 2010 email exchange between Arriva employees refers to a patient who "stated that he only answered the [ad] for the free meter."

163. Similarly, an April 2011 email from an Arriva customer service representative refers to a call with a patient "who thought the meter was free."

164. In an email from that same month, an Arriva sales team supervisor wrote that the "no cost guarantee" is "leading the patients to believe that [the meter] is free."

165. Arriva implemented its "no cost guarantee" as advertised.

166. In policy and practice, Arriva provided all new customers a new glucometer and submitted claims to Medicare for each new glucometer provided to Medicare beneficiaries, even where it knew or should have known that a particular beneficiary had received a glucometer paid for by Medicare within the last five years.

167. If Medicare denied the claim (typically because it caught a violation of the Five Year Rule), the beneficiary was never sent a bill for the glucometer – essentially receiving a "no cost" or "free" meter, as advertised by Arriva. Arriva routinely wrote off the cost of such glucometers as part of its periodic "mass write offs," which occurred as frequently as every month.

168. This practice is codified in numerous internal Arriva emails.

169. For example, in a September 2011 email, Ted Albin, Arriva's reimbursement consultant, explained that "if we are denied for the meter, we will write it off."

170. Similarly, in an October 2012 email, Robert Emerson, Arriva's head of

reimbursement, explained that if a claim for a glucometer is "rejected by Medicare as too soon; less than 5 years—then yes it's free."

171. In a November 2011 email, an Arriva sales team supervisor explained that: "We will never balance transfer a patient if we are denied for the meter."

172. In a March 2011 email, Arriva's head of customer service explained that because of the "no cost guarantee": "If Medicare denies the claim, we will not bill the pt for the meter."

173. In a July 2012 email, an employee in Arriva's reimbursement team explained Arriva's policy that if Medicare has denied payment for a glucometer because of a violation of the Five Year Rule "we are to write off the meter."

174. In a February 2010 email, Albin described a "Mass Write Off" for patient balances where the "Patient had [a meter] in the last five years" — meaning that the meter was denied because of a violation of the Five Year Rule.

175. Similarly, a June 2013 email from an Arriva employee with the subject line "[write off] after Medicare's denial for Meter (first order only)" referred to the write-off codes "03" and "14," which could be used when there was a "bulk [write off] for the first order due to Medicare's denial."

176. A January 2014 internal Arriva document that listed write-off codes indicated that code "14" referred to write offs for when "patient has not waited long enough for product." This is a reference to the Five Year Rule.

177. A December 2015 email from a senior Arriva employee, on which Emerson was copied, stated that as late as 2015, and likely later, Arriva engaged in "mass write offs" for "no cost" glucometers for which Medicare had denied payment because of violations of the Five Year Rule. The email stated that in that particular "mass write off" Arriva wrote off more than $189,000

for the cost of glucometers for Medicare beneficiaries.

178. Moreover, as detailed in Section IV below, a review of Arriva's billing confirms that Arriva routinely wrote off the costs of glucometers that it advertised and provided to Medicare beneficiaries at no cost.

B. Scheme #2: Routine Waivers of Copayments

179. In addition to offering and paying kickbacks to Medicare beneficiaries in the form of "free" or "no cost" glucometers, Defendants offered and paid kickbacks to Medicare beneficiaries by routinely waiving copayment obligations.

180. From as early as 2009, and lasting until at least the time of the revocation of Arriva's billing number in November 2016, Defendants routinely waived copayments.

181. As detailed below, these copayment waivers came in multiple forms. But, at all times, the purpose was to induce Medicare beneficiaries to continue to purchase diabetic testing supplies from Arriva that would be paid for by Medicare.

i. Arriva Waived Copayments in Direct Response to Customer Complaints about Copayment Obligations

182. One of the effects of Arriva's marketing of its "free" or "no cost" meters was that beneficiaries often came to the conclusion that all of their diabetic supplies would be "free" or "no cost." In some instances, Arriva customer representatives explicitly told beneficiaries that their diabetic supplies were free.

183. This led to complaints from customers who thought that their diabetic testing supplies were free, including not only glucometers, but strips and lancets as well. These complaints were often accompanied by threats by beneficiaries to cancel their accounts with Arriva and purchase their diabetic supplies elsewhere.

184. This was a problem for Arriva. The entire purpose of the "no cost" glucometer

kickback scheme was to create a long term and highly profitable revenue stream from the sales of strips and lancets that would be paid for by Medicare.

185. Arriva's solution was to waive the copayment for diabetic testing supplies through a "courtesy adjustment" or "courtesy write off."

186. As Albin, Arriva's reimbursement consultant, explained in a May 2010 email: "As a rule, we should not be cancelling a customer because . . . they do not want to pay for the meter. In those cases, you can ask . . . [me] if a courtesy adjustment can be done to save the customer."

187. In a September 2011 email, Albin reiterated the policy: "If the patient calls in and complains stating they didn't think they would need to pay anything for the meter, we will write off the patient balance for the meter as a courtesy for the miss communication [sic]."

188. Emerson, who oversaw Arriva's reimbursement department, echoed this policy in an October 2012 email, in which he explained that "[if] Medicare pays then the beneficiary owes a copayment balance. But, [w]e do drop it if they press."

189. Arriva communicated this policy to its sales and customer service representatives. In a November 2011 email to Arriva's "intake" team, an Arriva sales team supervisor explained that:

> If a patient calls in stating they thought the meter would be free or their first order copay is too high (due to the meter) we will allow a one time courtesy writeoff for the meter to keep the patient happy.

190. In fact, Arriva had a form that sales representatives were directed to fill out to request a courtesy waiver where secondary insurance did not cover the copayment obligation. The form was innocuously titled "OON – OUT OF NETWORK – SECONDARY INSURANCE."

191. However, on its face, the out of network form directed that it was to be used when "the customer is threatening to cancel."

192. One completed version of the out of network form described the reason for the request for a copayment waiver was: "Pt received a bill. Pt was told everything free."

193. In another completed version of the out of network form, the explanation for the request for a copayment waiver was: "Patient received a bill from Arriva, Pt was told no charge. If Pt has to pay he would cancel the account and go to VA or Liberty."

194. In an "Invoice Inquiry Call Handling" instruction manual that Arriva distributed to its customer service representatives, Arriva directed that the out of network form be used where the customer threatened to cancel the account. Specifically, the manual provided that:

> If the patient threatens to cancel their account because his/her secondary insurance denied the claim, the agent should not argue with the patient, but rather offer the patient an Out-of-Network (OON).
> (emphasis in original)

195. Arriva also used its Financial Assistance Form ("FAF") — a form purportedly created to establish that a beneficiary was indigent, and thus, could potentially qualify for the "occasional" waiver of copayments under Medicare rules — as a pretext for waiving a patient copayment obligation where the beneficiary simply did not want to pay his or her copayment.

196. For example, in a March 2011 email exchange between an Arriva customer services representative and his supervisor, the customer representative wrote: "Patient does not want us calling [for a reorder] until someone can tell him why he has to pay $189.00. He mentioned like others that the supplies are free." The supervisor responded: "Medicare did not pay much because he needs to meet his deductible. He can fill out an FAF and this will be waived."

197. Similarly, a February 2011 email describing a customer service call with a patient, includes the following: "Patient refused order because of copay this first time: however [the customer service representative] was able to overcome objections with hardship form."

198. The use of the FAF to pre-textually justify copayment waivers to induce patients

not to cancel their accounts with Arriva is amply demonstrated by a January 2012 email exchange, on which Arriva's head of reimbursement and Arriva's head of customer service were copied.

199. In the initial email, an Arriva employee wrote to the group: "Pt not happy w/20% copay, did go to another supplier. Resending FAF."

200. Another Arriva employee replied to all writing: "MY THOUGHTS . . . IF PT WITH OTHER SUPPLIER WHY NOT CLOSE THE ACCT. . .SENDING OUT FAF IS NOT NECESSARY. . . FAF ONLY MEANS ARRIVA WRITING OFF COPAY…THANKS."

201. The first Arriva employee replied, explaining: "IF PT APPROVED FOR FAF WILL USE ARRIVA AS ONLY SUPPLIER. WON'T GO ELSEWHERE."

202. An employee in Arriva's reimbursement department then forwarded the exchange to Emerson and wrote: "This is our typical 'save' scenario. We already know the customer has ordered from another supplier(s) and yet now the account will remain open, we are forwarding a financial waiver form."

203. According to an internal Arriva email from January 2015 (on which Bob Emerson was copied), Arriva, under the direction and supervision of Alere, continued to make "courtesy write offs (thought no copay, was told no copay)" until at least 2015. That same email makes clear that Alere sought to track these types of write offs during this period.

204. Similarly, in March 2016, Bob Emerson circulated to Claudio Araujo, who at the time was an Alere employee with supervisory authority over Arriva, and others an excel spreadsheet that had the title "Alere Reimbursement Department Bad Debt Restructuring Plan." The document refers to "courtesy write offs" as a form of "bad debt," further indicating that Arriva (with Alere's approval) continued to provide courtesy write offs as late as March 2016 – just months before Arriva's billing number was revoked.

205. Arriva even had a specific "write off code" for "courtesy write off." The code was "01." Additionally, Arriva had write off codes for the OON form ("56") and the FAF Form ("13").

206. Arriva's waiver of copayments in direct response to customer complaints constitutes both an offer and payment of a kickback with the purpose of inducing purchases of diabetic testing supplies by Medicare beneficiaries.

ii. Arriva Did Not Take Reasonable Efforts to Collect Copayments

207. In addition to waiving copayments in direct response to (i) complaints from beneficiaries about having to pay those obligations and (ii) threats by beneficiaries to cancel their accounts and purchase diabetic supplies from other suppliers, Defendants also instituted a scheme of systematically and routinely waiving beneficiary copayment obligations.

208. Arriva effectively eliminated copayment obligations for thousands of Medicare beneficiaries by (1) failing to take reasonable efforts to collect copayments and (2) systematically and routinely waiving those copayment obligations for beneficiaries whose copayments were not paid for by secondary insurance.

209. Arriva's collection efforts were, at best, "very soft." As Albin explained in a November 2011 email, "our collection efforts on patient balances are very soft, we would never put time and effort into an aggressive collection."

210. In the first few years of Arriva's existence, it is unclear whether Arriva sent out invoices at all. At the very most, they were sent out "irregularly," according to Emerson, Arriva's head of reimbursement. It was not until 2013 (two years after Alere acquired Arriva, and four years after Arriva was founded), that Arriva began to send beneficiaries quarterly invoices that reflected patient balances (although not always accurately), such as copayment obligations.

211. Even when Arriva finally began to send out quarterly invoices, it made little to no

additional effort to collect beneficiary copayment obligations.

212. For most of its existence Arriva had no collections department or any group that was responsible for collecting beneficiary copayments. Arriva created a collections department in either late 2015 or 2016. But, it is not clear what that group actually did.

213. That is because, Arriva did not make out-bound calls to beneficiaries seeking the payment of beneficiary copayment obligations.

214. Nor did Arriva send out deficiency letters informing beneficiaries that they had outstanding copayment obligations that needed to be paid.

215. Nor did Arriva refer beneficiaries' accounts to collection agencies or other third parties who could have taken efforts on Arriva's behalf to collect copayments.

216. Other than to send out invoices, Arriva took little to no action to collect copayments.

217. Moreover, Arriva did not cancel beneficiaries' accounts because they failed to pay copayment obligations. According to Emerson, Arriva would only cancel a customer if the person explicitly stated that he or she would never pay the copayment. It did not matter how high the unpaid copayment amount became, or how long the beneficiary failed to pay his or her copayment obligations, Arriva did not cancel beneficiaries' accounts or refuse to sell them additional diabetic testing supplies.

218. Arriva had a policy of never cancelling a beneficiary's account for a billing reason.

219. In a May 2010 email from Arriva's head of customer service to Albin and others, the rule was explained this way: "Pts are never cancelled . . . for any billing reason."

220. Thus, a Medicare beneficiary could go years without paying his or her copayment for diabetic testing supplies purchased from Arriva, and not (1) be subject to any real affirmative

collection effort on Arriva's part, or (2) be under any threat of having his or her account cancelled or service discontinued by Arriva. This was the case from Arriva's opening in 2009 until its closing in December 2017.

221. The process was different if the customer was not a Medicare beneficiary or if the customer was otherwise responsible for the full amount for the diabetic testing supplies.

222. In October 2012, Alere held a "Medicare Billing Summit" that was attended by Emerson and Albin, who oversaw Arriva's Medicare reimbursement efforts, as well as persons involved in Medicare reimbursement for Alere Home Monitoring and Alere Toxicology.

223. A PowerPoint presentation from that summit that was jointly prepared by representatives from Alere and Arriva includes a section titled "Best Practices Copays." The presentation states: "Patient Co-Pay strategy is by mail only, unless the full balance is patient responsibility. Full balance claims are reviewed prior to write off. If payment is not received, patient may stop receiving services."

224. Thus, the presentation indicates that Arriva and Alere had a different process for the collection of patient balances where the patient was fully responsible for the cost of the diabetic supplies than when Medicare was primarily responsible. A "patient may stop receiving services," if the patient was fully responsible for the amounts due. But, if Medicare was paying, then the patient would not be cancelled for "any billing reason."

iii. Arriva Instituted a System that Led to the Systematic and Routine Waiver of Copayments

225. In addition to failing to take affirmative steps to collect copayments, Arriva had a robust program of routinely waiving copayment obligations for beneficiaries whose copayment was not covered by secondary insurance.

226. In policy and practice, Arriva waived beneficiary copayment obligations where (1)

the beneficiary's copayment obligation was considered small (the "Small Balance Copay Waiver Policy"), or (2) the beneficiary had received three invoices and did not pay the copayment (the "Three Statements Copay Waiver Policy").

227. Both of these policies were first codified in a written policy document — titled "Patient Payment Process" — that Arriva formally adopted in 2015. But these policies (or versions of them) existed and were implemented for many years before that, potentially as early as 2009, and were in effect at Arriva until its closing in December 2017. Alere – through Ryan Wettergren, an Alere employee who ran Arriva's compliance function on Alere's behalf – explicitly approved both policies.

228. Each of these policies — coupled with Arriva's largely non-existent collection efforts — had the effect of systematically eliminating many beneficiaries' copayment obligations.

a. Small Balance Copay Waiver Policy

229. Under the Small Balance Copay Waiver Policy, Arriva waived and wrote off "small" copayment balances as part of its periodic (often monthly) "mass write offs." Arriva, at times, wrote off "small" balances as quickly as a few weeks after the dates-of-service. According to Arriva documents, small balance write offs were done "automatically."

230. What was considered "small" changed over time. The 2015 written version of the policy defines "small" as $5. Other documents indicate that at other times Arriva officially defined "small" as $1 or less. However, as demonstrated in Section IV below, Arriva in fact wrote off copayment obligations as high as $35 on the basis that the balance was ostensibly "small." The reality was that Arriva used the Small Balance Copay Waiver Policy as a cover for its routine waiver of copayments of varying amounts.

231. The stated justification for the policy was that copayment amounts that were

"small" were not worth the effort to collect. In reality, this made no sense because small balances aggregated over time and, as detailed above, Arriva took virtually no efforts to collect copayments of any amount.

232. The real purpose and effect of the Small Balance Copay Waiver Policy was the routine and systematic waiver of beneficiary copayments.

233. Copayment obligations for individual orders of diabetic testing supplies can be fairly small, depending on the beneficiary's testing frequency. Thus, it is not uncommon, for a particular date-of-service, that the copayment obligation for an order of strips or lancets would be under $5 or less.

234. A beneficiary's copayment obligation, however, could easily grow above this threshold when the copayment for multiple dates of service are combined. Thus, a $5 copayment obligation can quickly turn into a $15 or $20 copayment obligation when a beneficiary makes a second or third order of diabetic testing supplies.

235. But, under Arriva's Small Balance Copay Waiver Policy, a beneficiary's copayment obligation did not have the opportunity to grow beyond the "small" threshold before being waived and written off. That is because a "small" balance for a particular date-of-service would be waived and written off by Arriva without Arriva as much as sending the beneficiary an invoice, much less allowing for that copayment obligation to grow past "small" by combining it with copayment obligations from subsequent orders.

236. The 2015 Patient Payment Process policy document formally adopts Arriva's long-standing policy that it would only make collection efforts (*i.e.* send invoices to beneficiaries) for patient balances that were not "small." Specifically, the document commands that Arriva will not seek to collect "patient balances of five dollars ($5) or less for a given date of service." This was

Arriva's policy and practice prior to 2015, including for amounts far larger than $5.

237. Arriva waived small balance copayment obligations as part of its periodic "mass write offs." The write off code for "small balance writeoff" was "02."

238. The effect of the Small Balance Copay Waiver Policy was that Arriva routinely and systematically waived copayments for diabetic testing supplies without as much as sending invoices to beneficiaries for copayments.

b. Three Statements Copay Waiver Policy

239. When Arriva did not waive copayment obligations pursuant to the Small Balance Copay Waiver Policy, it later waived them pursuant to the Three Statements Copay Waiver Policy.

240. Under the Three Statements Copay Waiver Policy, once a beneficiary received three (or, in many instances, less) invoices for a copayment for a particular date-of-service, Arriva could and, in most cases, would write off the copayment obligation. There were no other requirements for the waiver and write-off of these copayment obligations.

241. As codified in Arriva's Patient Payment Process policy document from 2015, which was approved by Arriva and Alere, the policy was: "After at least three (3) statements are sent for a given DOS [date-of-service] the claim balance will be written off as uncollectable with the appropriate adjustment code."

242. Emerson, Arriva's head of reimbursement, described the policy this way: "The policy was that we would bill them three times, and if the patient did not respond and we had billed them three times, then that balance could be written off." At bottom, according to Emerson: "People who had three statements would get a write-off."

243. The reality was that Arriva rarely sent three invoices before waiving beneficiaries' copayment obligations. As demonstrated in Section IV below, beneficiaries did not systematically

or routinely receive invoices – much less three invoices – seeking payment of their copayment obligations. Rather, a particular patient could receive no invoices, or just one or two invoices, sometimes years after the relevant date-of-service, before Arriva waived the copayment obligation. Some beneficiaries went years without receiving any invoice from Arriva seeking payment of copayment obligations, which Arriva ultimately wrote off as part of its routine "mass write offs."

244. Alere had a similar policy, which it encouraged Arriva to adopt. For example, in a June 2013 email sent by an employee of Alere Home Monitoring to Emerson in the wake of the "Medicare Billing Summit," the Alere employee described the Alere copayment write off policy to Emerson the following way: "We . . . send up three statements and then write off the copays."

245. Thus, if, after having been sent three (or less) invoices, a beneficiary simply failed to pay a copayment for the purchase of diabetic testing supplies on a particular date-of-service, like Alere, Arriva would waive and write off the copayment.

246. Arriva routinely wrote off these copayments as part of its periodic (often monthly) "mass write offs." In the early years, it did these types of write offs as part of "mass write offs" for "remaining contractual balance – Mass W/O," which was code "03." In later years, Arriva created a write off code for "3 Statements No Payment," which was "84." It may have used other write off codes.

247. For example, in December 2015, using code 84, Arriva engaged in a "mass write off" of copayments pursuant to the Three Statements Copay Waiver Policy, totaling more than $2.2 million in written off copayment obligations.

248. Before waiving and writing off a beneficiary's copayment obligation pursuant to the Three Statements Copay Waiver Policy, Arriva did not make any real effort, other than sending out invoices, to collect the copayment. It did not confirm that the beneficiary could not or would

not pay the copayment. Nor did Arriva discontinue or otherwise interrupt service to the beneficiary.

249. Under the Three Statements Copay Waiver Policy, Arriva could and would waive the copayment for a particular beneficiary over and over again for different dates-of-service. Thus, if a beneficiary received three (or, often less) invoices for his or her first order of diabetic testing supplies from Arriva and did not pay the copayment, Arriva would waive that copayment as part of a periodic "mass write off." It would do so again for the second order, and the third order, and so on, as long as three invoices were sent for those particular orders — and Medicare continued to pay for the items.

250. The effect of this — coupled with Arriva's non-existent collection efforts and refusal to cancel customers for failure to pay copayments — was that a beneficiary could go years without paying copayments for any order, and simply because the beneficiary received three statements for each date-of-service, each of those copayment obligations would systematically and routinely be waived and written off by Arriva.

251. Not surprisingly, beneficiaries who did not have to pay copayments continued to purchase diabetic supplies from Arriva. As advertised, those items were "free" or "no cost" to the beneficiary. The entire cost for the diabetic supplies was borne by Medicare, and ultimately taxpayers.

C. Defendants' Knowingly and Willfully Paid Kickbacks to Medicare Beneficiaries and Recklessly Submitted Claims to Medicare that Were Tainted by Kickbacks

252. As a threshold, not surprisingly given the steady stream of Medicare guidance, Defendants knew about Medicare restrictions on the payment of kickbacks to beneficiaries.

253. Emerson and Albin, both of whom headed Arriva's reimbursement efforts at different times, together had decades of experience in Medicare reimbursement, and, thus, were

knowledgeable about Medicare payment rules. As Emerson explained, "I think I have a pretty good understanding of the rules."

254. Defendants specifically understood that routine copayment waivers were not permitted. As Emerson succinctly put it: "no-pay is not okay." Albin understood that "routine" waiver of copayments are not permitted.

255. According to Emerson, head of reimbursement for Arriva and Alere Home Monitoring, "my understanding is that you cannot have a pattern of routinely waiving copays of patients." This is because "Medicare felt that they should not be made the sole payor in this, that if you're doing that, if you're making Medicare the sole payor, then the amount that's being charged is incorrect and you may as well charge the 80 percent."

256. Thus, Defendants knew that the payment of kickbacks to Medicare beneficiaries was unlawful and that Medicare would not pay for claims that were tainted by unlawful kickbacks.

257. Notwithstanding this, Defendants knowingly and willfully offered and paid kickbacks to Medicare beneficiaries in the form of "free" or "no cost" glucometers and the waiver of beneficiary copayment obligations. They did this for the purpose of creating revenue and profit streams from the sale of strips and lancets that were paid for by insurance, specifically Medicare.

258. A 2015 email from an Arriva vice president of operations explained: "To be clear, if the strips and lancets are paid by the patients' insurance we want to service these patients. The other items [meters and lancing devices] are not a significant enough cost to hold up the order and they are needed for the patient to use the strips and lancets, therefore we should ship these at no charge if not covered."

259. Other documents and statements from Arriva employees and others make clear that Defendants understood that their conduct was unlawful.

260. For example, in a January 2013 email on which Emerson was copied, an employee in Arriva's reimbursement department, declared the following: "It is a serious Medicare offense to indicate that there would be no out of pocket expense to the patient, it's considered coercion . . . and, in fact, it is. It appears to me that the sales team is 'making the sale' at all costs, and this is not OK with Medicare."

261. According to Tim Stocksdale, Arriva's original co-owner, Arriva was "aware . . . that Medicare was cracking down [on]. . . advertising [a] free meter but then billing for the meter, or advertising free diabetic supplies and billing for the diabetic supplies."

262. Arriva employees shared with Arriva's management their belief that Arriva's commercials and marketing materials were leading prospective customers to believe that Arriva's diabetic testing supplies were free.

263. For example, as early as 2011 or 2012, and periodically thereafter, Emerson complained to Wallace, Chip Stocksdale, as well as others in Arriva's senior management, about Arriva's television commercial. As Emerson put it, "I questioned the television commercial."

264. According to Emerson: "My concern was that it's possible a customer can misunderstand and think they're getting a free product."

265. An Arriva customer service manager, also raised concerns regarding the commercial, including during Arriva's weekly management meetings, which were attended by Arriva's senior management, including, Wallace and Chip Stocksdale.

266. For example, in an August 2012 email to, amongst others, Emerson and Chip Stocksdale, the customer service manager expressed her frustration that Arriva's television commercial was leading customers to believe that their diabetic testing supplies were free. She wrote the "commercial clearly [states] . . . 'call us now for your testing supplies and receive one

of these meters for FREE." She continued, "we need to change the verbiage of the commercial."

267. These concerns about Arriva's commercial were ignored by senior management of Arriva and Alere because, as Emerson put it, "their commercial was a successful commercial." Versions of Arriva's television commercial ran from 2010 until at least 2015.

268. Emerson also complained to senior management at Arriva and Alere, including Wallace, Chip Stocksdale, and Araujo about Arriva's poor collection efforts.

269. For example, starting in 2012, Emerson complained that Arriva was not regularly sending patients invoices that reflected their copayment obligations; recognizing Arriva's obligation, at the very minimum, to make some effort to collect copayments.

270. In response, Arriva began sending quarterly invoices sometime in 2013 (four years into its existence), but undermined those efforts by routinely waiving copayment obligations.

271. Starting in 2013, Emerson complained that Arriva was not making out-bound calls to beneficiaries seeking payment of copayment obligations.

272. Arriva never instituted out-bound calls to collect copayments.

273. Emerson also complained to Chip Stocksdale and Araujo about Arriva's policy and practice of not discontinuing or suspending service of patients who did not pay their patient balances, including copayment obligations. As Emerson put it: "I felt like there was no incentive for the patient to pay if they thought they were going to receive supplies."

274. Emerson was told that the issue "had been vetted"; and, consequently, the policy did not change.

275. As Emerson explained in a June 2013 email to an employee at Alere Home Monitoring, Emerson's former employer "National Diabetic Pharmacies/Liberty" had a "different" more robust collection policy. According to Emerson, that company, sent multiple

letters informing the beneficiary of a "new balance." If that did not lead to payment of the copayment obligation, then, outbound "dialer campaigns" were initiated, during which the beneficiary was informed that "if we did not receive their copay within 15 days their account would unfortunately be put on hold." If that did not work, beneficiaries in fact "had their accounts put on hold." If the patient paid the copayment obligation, all was forgiven. If not, a "broken promise letter" was sent cancelling the account. A "dedicated collections team" was hired to ensure the collection of copayments.

276. Thus, Arriva and Alere were well-aware of what was required to make a more than token collection effort. They simply decided not to implement such efforts at Arriva because it was not consistent with their kickback scheme and their need to preserve the flow of Medicare money to pay for the diabetic supplies Arriva sold to Medicare beneficiaries.

277. Contemporaneous emails also establish that Arriva employees complained of Arriva's practice of waiving copayments in response to customer complaints about paying the amounts that were due.

278. For example, in a June 2014 email, an employee in Arriva's reimbursement department sent an email to Emerson complaining about Arriva's practice of waiving copayment obligations. The Arriva employee stated in her email: "I just received an email to post a [write off] on a pharmacy account because the patient feels it is too much. For me, it goes against everything that I have learned in the reimbursement field."

279. Moreover, Defendants were well aware that Arriva had an abnormally low collection rate for copayment obligations. For example, in advance of the Arriva/Alere "Medicare Billing Summit," in October 2012, Albin sent an email to a senior executive at Alere, copying Emerson, which contained an attachment with Arriva's "medicare stat sheets."

280. The "stat sheets," which had been created by Albin, had a column for "% of Patient Co-pays Collected." The column indicated a patient copay collection rate of "10%."

281. There was a separate column for "Annual Patient Co-pay Write-offs." The amount indicated in the column was "$1,200,000.00."

282. In fact, according to Albin, as of 2011, Arriva had "a hundred million dollars" worth of unpaid patient balances, including unpaid copayment obligations that had built up over the years.

283. Even after Arriva and Alere became aware in 2014 of the investigation that led to the filing of this Complaint-in-Intervention, Arriva continued to waive copayment obligations, at least in the context of Arriva's pharmacy business.

284. For example, on April 22, 2016, an Arriva employee, sent an email making a request to "please waive the copay . . . because [the patient] don't want to pay it. [*sic*]" The response was: "Copay of $11.60 has been written off."

285. Similarly, in a February 2016 email, an Arriva employee again sought a copay waiver because "Pt received the invoice and don't want to pay the copay. [*sic*]" Arriva's pharmacy reimbursement manager responded "Copay has been waived."

286. In fact, it appears that Arriva and Alere planned to continue to expand their copayment waiver efforts. In April 2016, two individuals who worked with Arriva and Alere on business development, exchanged by email a PowerPoint presentation regarding a "Connected Meter Program" that had the monikers for both Alere and Arriva on the front cover.

287. In the body of the presentation, there was a bullet point for "Sales/Mktg," which further included a discussion point for "Incentives – copay waiver, etc."

288. The program was never implemented, in part, because Arriva's billing number was

suspended by CMS in November 2016.

289. Thus, even in the face of a federal investigation of their kickback scheme, Arriva, with Alere's supervision and approval, continued to routinely waive copayments. This further establishes that Defendants knowingly and willfully paid kickbacks to Medicare beneficiaries, and recklessly submitted claims tainted by those kickbacks to Medicare.

D. Violations of the AKS Are Material to the United States' Payment Decisions

290. Whether a claim to Medicare is tainted by an unlawful kickback is material to the United States' decision to pay that claim.

291. Congress has determined that, as a matter of law, claims that are tainted by violations of the AKS "constitute false or fraudulent" claims; and, thus whether a claim is tainted by an unlawful kickback is, as a matter of law, material to the United States' payment decision. 42 U.S.C. § 1320a-7b(g).

292. Consistent with this requirement imposed by Congress, CMS has also made clear that violations of the AKS are material to the United States' payment decisions. For example, the CMS 1500, a Medicare claim form, includes an express certification from the party submitting the claim that "the claim . . . complies with . . . the Federal anti-kickback statute."

293. The materiality of AKS violations to Medicare payment decisions is consistent with the fact that the AKS is a criminal statute specifically targeted at preventing healthcare fraud in the context of federal health care programs such as Medicare.

294. Moreover, a provider is subject to mandatory exclusion from Medicare if criminally convicted of an AKS violation, 42 U.S.C. §§ 1320a–7(a)(1), (3), and subject to permissive exclusion if HHS determines that the provider "has committed an act" prohibited by the AKS, *id.* §§ 1320a-7a(a)(7); 1320a–7(b)(7).

295. CMS and HHS-OIG have each made clear that providers' waiver of copayment

obligations or other payment of kickbacks to Medicare beneficiaries constitute violations of the AKS and FCA, and, thus, are material to Medicare payment decisions.

296. For example, the Medicare Claims Processing Manual states that "suppliers who routinely waive the collection of deductible or coinsurance from a beneficiary constitute a violation of the law pertaining to false claims and kickbacks. These situations should be referred to Program Integrity area for additional investigation . . . ." MEDICARE CLAIMS PROCESSING MANUAL, Chapter 23, § 80.8.1.

297. For its part, HHS-OIG has issued multiple fraud alerts going back decades warning that the routine waiver of Medicare copayment obligations will lead to liability under the AKS and FCA. *See, e.g.*, OIG Special Fraud Alert, 59 Fed. Reg. 65372-01 (Dec. 19, 1994); 79 Fed. Reg. 59717, 59720 (Oct. 3, 2014).

298. As HHS-OIG has explained, the payment of kickbacks to a Medicare beneficiary, including in the form of a copayment waiver, is unlawful and thus material to Medicare payment decisions because the provider "may be unlawfully inducing that patient to purchase items or services from [it]." OIG Special Fraud Alert, 59 Fed. Reg. 65372-01 (Dec. 19, 1994). Moreover, the waiver of copayments causes Medicare to "pay[] more for an item . . . than it should" and, in many cases, "for unnecessary items." *Id.* This results in there being "less Medicare funds available to pay for truly needed services." *Id.*

299. Additionally, for years, the United States has sought and obtained damage awards and settlements totalling over $1 billion dollars under the FCA for claims that were submitted to Medicare that were tainted by kickbacks in violation of the AKS, including for routine copayment waivers. For example:

(a) In 2012, Texas-based Orthofix, Inc., a medical device manufacturer, agreed to pay

over $34 million to resolve allegations that, among other things, it waived patient copayments, thus misstating their true cost and resulting in overpayments by federal programs. *See* Orthofix Press Release (June 7, 2012), *available at* https://www.justice.gov/opa/pr/texas-based-medical-device-manufacturer-pays-us-34-million-settle-false-claims-act.

(b) In 2015, North Carolina-based Physician Pharmacy Alliance, Inc. agreed to pay $5 million to resolve allegations that it routinely waived copayments of Medicare and Medicaid patients. *See* Physician Pharmacy Alliance, Inc. Press Release (May 6, 2015), *available at* https://www.justice.gov/usao-ednc/pr/pharmacy-company-agreed-pay-5-million-settle-claims-it-gave-gift-cards-and-waived.

(c) In 2016, Nashville Pharmacy Services in Tennessee agreed to pay up to $7.8 million to resolve allegations that it, among other things routinely and improperly waived TennCare and Medicare beneficiaries' copayments. *See* Nashville Pharmacy Services Press Release (Jan. 5, 2016), *available at* www.justice.gov/usao-mdtn/pr/nashville-pharmacy-services-settles-false-claims-act-lawsuit.

(d) In 2016, a Florida cardiologist Asad Qamar and the Institute of Cardiovascular Excellence agreed to pay $2 million and release any claim to $5.3 million in suspended Medicare funds to resolve allegations that they, among other things, paid kickbacks to patients by waiving Medicare copayments irrespective of financial hardship. *See* Institute of Cardiovascular Excellence Press Release (June. 30, 2016), *available at* https://www.justice.gov/opa/pr/florida-cardiologist-and-his-practice-pay-millions-and-agree-three-years-exclusion-resolve.

(e) In 2016, Hudson Valley Associates, R.L.L.P, a New York-based medical practice,

agreed to pay $5.31 million to resolve allegations that it, among other things, routinely waived Medicare beneficiaries' copayments without an individualized documented determination of financial hardship or exhaustion of reasonable collection efforts. *See* Hudson Valley Associates, R.L.L.P Press Release (Oct. 21, 2016), *available at* https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-531-million-civil-settlement-against-hematology.

(f) In 2017, Quest Diagnostics Inc. agreed to pay $6 million to resolve allegations that Berkeley HeartLab Inc., a California-based blood testing lab, among other things, paid kickbacks to beneficiaries of federal health care programs by routinely waiving copayments. *See* Quest Diagnostics Inc. Press Release, (May 2, 2017), *available at* https://www.justice.gov/usao-sc/pr/blood-testing-laboratory-pay-6-million-settle-allegations-kickbacks-and-unnecessary.

(g) In 2017, nationwide pharmacy DaVita Rx, LLC agreed to pay $63.7 million to resolve allegations that, among other things, it routinely wrote off unpaid beneficiary copayment debt and extended discounts to beneficiaries who paid for their medications by credit card. *See* DaVita Press Release (Dec. 14, 2017), *available at* www.justice.gov/opa/pr/davita-rx-agrees-pay-637-million-resolve-false-claims-act-allegations.

(h) In 2017, United Therapeutics Corporation, a Maryland-based pharmaceutical company, agreed to pay $210 million to resolve allegations that it used a foundation as a conduit to pay the copayment obligations of Medicare patients taking its pulmonary arterial hypertension drugs. *See* United Therapeutics Corporation's Press Release (Dec. 20, 2017), *available at* https://www.justice.gov/opa/pr/drug-maker-united-

therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability.

(i) In 2018, New York-based drug maker Pfizer agreed to pay $23.85 million to resolve claims that it used a foundation as a conduit to pay for Medicare patients' copayments for taking three Pfizer drugs. *See* Pfizer Press Release (May 24, 2018), *available at* www.justice.gov/opa/drug-maker-pfizer-agrees-pay-2385-million-resolve-allegations-it-paid-kickbacks-through-copay.

(j) In 2018, Lincare, Inc., a durable medical equipment supplier based in Clearwater Florida, agreed to pay $5.25 million to resolve allegations that it attempted to gain a competitive advantage in the marketplace by unlawfully waiving or reducing co-insurance, co-payments, and deductibles for beneficiaries who participated in a Medicare Advantage Plan operated through a private insurer. *See* Lincare, Inc. Press Release (Aug. 16, 2018), *available at* https://www.justice.gov/usao-sdil/pr/durable-medical-equipment-provider-lincare-pays-525-million-resolve-false-claims-act.

(k) In 2018, California-based drug maker Actelion Pharmaceuticals US, Inc., agreed to pay $360 million to resolve allegations that it illegally set up a fund to pay for patient copayments for Actelion's own drugs. *See* Actelion Press Release (Dec. 6, 2018), *available at* www.justice.gov/opa/pr/drug-maker-actelion-agrees-pay-360-million-resolve-false-claims-act-liability-paying.

(l) In 2018, Glades Drugs, Inc., a pharmacy located in Palm Beach County, Florida, agreed to pay $300,000 to resolve allegations that it waived or failed to collect required copayments from Medicare and TRICARE beneficiaries. *See* Glades Drugs, Inc. Press Release (Dec. 18, 2018), *available at* https://www.justice.gov/usao-sdfl/pr/glades-drugs-agrees-pay-united-states-300000-settle-allegations-fraudulent-claims.

(m) In 2019, Stark Pharmacy in Kansas agreed to pay $9.5 million to resolve allegations that, among other things, it improperly waived or reduced patient copayments. *See* Stark Pharmacy Press Release (Jan. 30, 2019), *available at* www.kansascity.com/news/business/health-care/article225251405.html.

(n) In 2019, Pentec Health, Inc., Pennsylvania based pharmacy, agreed to pay $17 million to resolve allegations that it, among other things, routinely waived patient copayments and deductible obligations for Medicare and VA beneficiaries. *See* Pentec Health, Inc. Press Release (Feb. 4, 2019), *available at* https://www.justice.gov/usao-edpa/pr/pentec-health-inc-pay-17-million-settle-false-claims-act-allegations.

(o) In 2019, three pharmaceutical companies – Jazz Pharmaceuticals, PLC, Lundbeck, LLC, and Alexion Pharmaceuticals, Inc. – agreed to pay $122.6 million to resolve allegations that they illegally paid copayments owed by Medicare beneficiaries for their own products. *See* Three Pharmaceutical Companies Press Release (April 4, 2019), *available at* www.justice.gov/opa/pr/three-pharmaceutical-companies-agree-pay-total-over-122-million-resolve-allegations-they-paid.

(p) In 2019, two pharmaceutical companies – Astellas Pharma US Inc. (Astellas) and Amgen Inc. (Amgen) – agreed to pay $124.75 million to resolve allegations that they illegally paid copayments owed by beneficiaries of Medicare for their own products. *See* Three Pharmaceutical Companies Press Release (April 25, 2019), *available at* https://www.justice.gov/opa/pr/two-pharmaceutical-companies-agree-pay-total-nearly-125-million-resolve-allegations-they-paid.

(q) In 2019, US WorldMeds LLC, a Kentucky-based pharmaceutical company, agreed to pay $17.5 million to resolve allegations that it, among other things, illegally paid

copayments owed by beneficiaries of Medicare and TRICARE for one of its drugs through a third-party foundation, while substantially increasing the cost of the drug. *See* US WorldMeds LLC Press Release (April 30, 2019) *available at* https://www.justice.gov/opa/pr/pharmaceutical-company-agrees-pay-175-million-resolve-allegations-kickbacks-medicare-patients.

300. In addition, for years, the United States has brought criminal charges and obtained convictions for violations of the AKS, including for routine copayment waivers and other offers of free items to Medicare beneficiaries. For example:

(a) In 1992, a federal jury in Kentucky found a husband and wife guilty of mail fraud for, among other things, waiving copayments owed to a dental insurance plan. *See United States v. Nichols*, 1992 WL 238264 (6th Cir. Sept. 25, 1992).

(b) In 2012, a federal jury in Texas found a woman guilty of conspiring to commit health care fraud for her role in telling Medicare beneficiaries that they would receive arthritis kits for free, at no cost to them. *See United States v. Turner*, 561 Fed. Appx. 312 (5th Cir. 2014).

(c) In 2017, Jason May and Gerald Jay Schaar, co-owners of Advantage Pharmacy, were criminally charged and later pled guilty in Mississippi to conspiracy to defrauding TRICARE and other federal healthcare programs for, among other things, failing to collect patient copayments or paying copayments on behalf of beneficiaries. *See* May and Schaar Press Release (July 13, 2017), *available at* https://www.justice.gov/usao-sdms/pr/two-charged-multi-million-dollar-compounding-pharmacy-fraud-scheme.

(d) In 2018, Terry Lynn Anderson and Rocky Freeland Anderson were convicted of conspiracy to commit health care fraud in Texas for, among other things, inducing

patients to purchase hearing aids by promising them that the hearing aids would be provided to them at "no cost," and that applicable copayments, coinsurance, or deductibles would be waived. *See* Anderson Press Release (Mar. 9, 2018), *available at* https://www.justice.gov/usao-ndtx/pr/father-and-son-convicted-following-trial-167-million-health-care-fraud-scheme.

(e) In 2019, Thomas Edward Spell, Jr., who operated pharmacies across the United States, pled guilty in Mississippi to defrauding TRICARE and other federal healthcare programs for, among other things, waiving TRICARE's requirement that a beneficiary make a copayment to receive medicine. *See* Thomas Edward Spell, Jr. Press Release (Aug. 9, 2018), *available at* https://www.justice.gov/usao-sdms/pr/pharmacy-owner-pleads-guilty-part-largest-health-care-fraud-case-ever-mississippi-0.

(f) In 2019, a federal jury in Nashville, Tennessee found a former CEO of a Tennessee pain management company guilty for his role in an illegal kickback scheme involving approximately $4 million in tainted durable medical equipment claims to Medicare. *See* John Davis Press Release (Apr. 4, 2019), *available at* https://www.justice.gov/opa/pr/former-ceo-tennessee-pain-management-company-convicted-role-approximate-4-million-medicare.

301. Additionally, this year, in addition to this action, the United States has filed suit against multiple parties under the False Claims Act for violations of the AKS in the form of copayment waivers. For example:

a. On June 5, 2019, the United States filed a complaint-in-intervention under the False Claims Act against Mallinckrodt ARD LLC, a large pharmaceutical company, alleging that Mallinckrodt used a foundation as a conduit to pay illegal kickbacks

in the form of copay subsidies for Acthar so it could market on its drugs as "free" to doctors and patients while increasing its price. *See* Mallinckrodt ARD LLC Press Release (Jun. 3, 2019) https://www.justice.gov/opa/pr/united-states-intervenes-false-claims-act-lawsuit-against-drug-maker-mallinckrodt-alleging.

b. On June 14, 2019, the United States filed a complaint-in-intervention against Smart Pharmacy Inc., and SP2 LLC, two compounding pharmacies located in Jacksonville, Florida. The complaint alleges, among other things, that the pharmacies routinely waived patient copayment obligations. *See* Smart Pharmacy Inc., and SP2 LLC Press Release (Jun. 14, 2019) https://www.justice.gov/opa/pr/united-states-files-false-claims-act-complaint-against-two-compounding-pharmacies-and-their.

302. In April 2019, former Arriva executives David Wallace and Timothy Stocksdale entered into a settlement in which they agreed to pay the United States $500,000 each – for a combined total of $1 million – to resolve allegations about their role in Arriva's scheme during the period from November 23, 2011 through August 30, 2013 after Alere purchased Arriva. *See* Wallace and Stocksdale Press Release (Apr. 24, 2019), *available at* www.justice.gov/usao-mdtn/pr/two-former-arriva-medical-executives-agree-pay-1-million-settle-diabetic-testing-supply.

303. Moreover, DOJ has also intervened in the present action against Arriva and Alere in which the United States alleges that they were damaged and are entitled to recoup monies that were improperly paid to Arriva for claims tainted by kickbacks.

304. Given the above, a reasonable person would have known that whether a claim is tainted by a kickback is material to the United States' decision to pay the claim. Moreover, as

detailed in the previous section, Defendants in fact knew that this was material to the United States' decision to pay Medicare claims.

III. Defendants Submitted False Claims to Medicare for Glucometers in Violation of the Five Year Rule

305. In connection with offering and paying kickbacks to Medicare beneficiaries in the form of "free" or "no cost" glucometers, Arriva submitted false claims to Medicare for glucometers in violation of the Five Year Rule.

306. Arriva had a policy of requiring all new patients to receive a new glucometer with initial orders — whether the beneficiary needed or wanted the glucometer or not.

307. This policy was set out in a July 2013 email from an Arriva sales team supervisor, explaining: "We will send a meter with every order." The sales team supervisor further explained that: "If they say that they don't want a meter, advise them that all new start orders come with everything."

308. Before billing Medicare for glucometers provided to beneficiaries on a "no cost" basis, Arriva made no effort to determine whether beneficiaries who had received new glucometers from Arriva had, within five years, received a meter that had been paid for by Medicare.

309. As a policy and practice, Arriva never asked beneficiaries if they had received a glucometer within the previous five years, much less whether that meter had been paid for by Medicare. As Tim Stocksdale explained, "I don't believe that we asked patients if they had received a meter or if they know if Medicare . . . had paid for a meter at some point in the previous five years."

310. Nor, where Arriva had access to patient and billing records for diabetic testing companies that it had acquired, did Arriva check its own records to determine whether beneficiaries had received a glucometer within the last five years.

311. This was in conflict with guidance from Medicare contractors who processed DME claims that, as part of the intake process, suppliers should inquire about a beneficiaries' history of similar items.

312. For example, the March 2010 supplier manual for durable medical equipment published by Medicare contractor National Government Services (NGS), which processed DME claims for Medicare, explained that "[i]t is the responsibility of the beneficiary and supplier to coordinate with all the involved parties to ensure that equipment is only provided when it is medically necessary and to determine [that] the equipment provided the patient is not a duplication of previously obtained equipment."

313. The NGS supplier manual further advised that "Providers should evaluate the patient's history during the intake process to determine if the same/similar equipment was previously obtained."

314. Similarly, the March 2010 supplier manual for durable medical equipment published by Medicare contractor Noridian Administrative Health Services LLC ("Noridian"), which processed claims for DME for Medicare, directed that, to avoid violations of the Five Year Rule: "Suppliers should ask very specific questions when providing items to Medicare patients. The supplier should determine information such as . . . If the beneficiary currently has or had an identical or similar item in the past . . . When the beneficiary received the items and if the items have been returned . . . ."

315. In support of this direction, since at least 2010, Noridian has published a "Suggested Intake Form" that includes numerous model questions designed to assist a supplier in determining whether within the last five years Medicare has provided the beneficiary with a same or similar item for which the supplier intends to provide to the beneficiary and bill to Medicare. The

suggested questions include the following:

- Has the beneficiary ever received the same or similar supplies/equipment?
- If yes, list equipment/supplies:
- Who was it purchased or rented from?
- Date purchased or if rented, how many months?
- Was item returned to original supplier?
- Is the item being replaced?
- Is there a new medical necessity?
- Describe condition for previous need:
- Describe new/changed condition:

316. Medicare contractor CGS, which has processed DME claims for Medicare, has published a similar "Suggested Intake Form," which include virtually identical model questions.

317. The reasons for Arriva's knowing violation of the Five Year Rule are twofold. First, Arriva's kickback scheme required the provision of a "free" or "no cost" meter to beneficiaries. Thus, every new or initial order needed to include a glucometer to pay the kickback to the beneficiary.

318. Second, Arriva needed to ensure that all new customers had the particular glucometers for which Arriva sold testing strips. Pursuant to contracts with manufactures of diabetic testing supplies, Arriva sold a limited number of brands of diabetic testing supplies. In order to make sure that beneficiaries had the exact type of glucometer for which Arriva sold testing strips, Arriva needed to include the appropriate glucometer with a beneficiary's initial order.

319. Arriva submitted claims (certifying its compliance with Medicare billing rules, including the Five Year Rule) to Medicare for every glucometer provided to a new customer who

was a Medicare beneficiary, even where it knew or could easily have determined that the beneficiary had received a meter paid for by Medicare within the past five years.

320. In a November 2011 email, a sales team supervisor succinctly explained the policy: "We will bill for all first order meters."

321. Arriva submitted these claims even though it was well aware of the Five Year Rule. As Emerson, Arriva's head of reimbursement explained: "My understanding is that Medicare will not pay for DME [any] more than one time in a five-year period." Albin had a similar understanding: "They do not pay for a meter that was supplied in the past five years." As did Tim Stocksdale: "Medicare will only pay for a new glucose meter every five years."

322. Emerson objected to Arriva submitting claims to Medicare in violation of the Five Year Rule. As he explained it: "The five-year meter, I said that I thought that we should not be pursuing the submission of the claim because . . . Medicare was saying, No, we're not going to pay this anymore . . . ."

323. Medicare typically rejected Arriva's claims for new glucometers when the beneficiary had received a glucometer paid for by Medicare within the previous five years, and thus the Five Year Rule had been violated (although, a number of these false claims were not caught by Medicare, and were paid in full).

324. In fact, according to Albin, Arriva's reimbursement consultant, Arriva's rejection rate for claims that violated the Five Year Rule was as high as "40 percent."

325. Thus, Arriva knew that Medicare would deny claims that Medicare knew violated the Five Year Rule, and did so for a very large number of the claims that Arriva submitted to Medicare.

326. Notwithstanding their knowledge that as many as 40 percent of the glucometers for

which Arriva submitted claims to Medicare were denied for violation of the Five Year Rule, Defendants did not change Arriva's policy and practice of (i) providing all new customers with a new glucometer, (ii) not inquiring with beneficiaries whether those beneficiaries had received glucometer paid for by Medicare within the past five years, (iii) submitting claims to Medicare for all first order meters sold to Medicare beneficiaries, and (iv) writing off the claim amounts for the denied claims.

327. Instead, Defendants, at minimum, deliberately ignored and recklessly disregarded whether beneficiaries had received a meter paid for by Medicare within the past five years. Defendants' position was that Medicare's claims review process would figure out which claims violate the Five Year Rule, and which do not, and, thus, Arriva did not need to take any steps to determine whether claims that it submitted to Medicare violated the Five Year Rule.

328. As a supervisor of the Arriva sales team explained in a June 2013 email: "I'm sure Medicare won't pay for the meter if they have already paid for it within the last 5 years. It would be an automatic denial. We have to bill, but once it's denied we incur the cost that we paid for the meter and write off the rest that Medicare would have paid."

329. Violations of the Five Year Rule are material to CMS's decision to pay a claim. Payment for DME that violates the Five Year Rule is explicitly prohibited by statute. *See* 42 U.S.C. § 1395m(a)(7)(C)(ii). Medicare does not pay for claims that violate the Five Year Rule, making this a condition of payment. As Arriva itself recognized, this "would be an automatic denial." In fact, over the years, Medicare denied tens of thousands of claims for glucometer reimbursement submitted by Arriva that violated the Five Year Rule. To the extent that such claims were not denied, it was because Medicare inadvertently failed to catch the Five Year Rule violation in every single instance. Medicare's policy at all relevant times was that it did not pay

for glucometers that violated the Five Year Rule because such items are not covered by Medicare.

330. Given this clear statutory prohibition for the payment of claims that violate the Five Year Rule, a reasonable person would know that whether the Five Year Rule was violated is material to the United States' payment decisions for such claims. Moreover, as detailed above, Defendants in fact knew that whether Five Year Rule was violated was material to the United States' decision to pay Medicare claims.

331. CMS denied the majority of claims that were submitted by Arriva that violated the Five Year Rule. The ones that were not denied were approved in error.

IV. Specific Examples of False or Fraudulent Claims

332. The following paragraphs set forth examples of false claims and/or false statements to Medicare.

333. A review of a representative sample of Arriva's claims indicates that those claims were tainted by kickbacks to Medicare beneficiaries in the form of (a) "free" or "no cost" glucometers, and (b) the routine and systematic waiver of beneficiary copayment obligations.

334. A review of all of Arriva's claims further indicates that Arriva billed for glucometers in violation of the Five Year Rule and at times received improper payments for thousands of such glucometers when Medicare's payment system failed to automatically notice and "catch" the violation.

335. Attached to and made part of this Complaint is Exhibit A, which contains a summary chart of 40 false claims regarding four Medicare beneficiaries in this action. The claims identified in Exhibit A are illustrative samples of the types of false claims submitted or caused to be submitted to Medicare between April 1, 2010 and at least November 30, 2016 by Defendants.

336. For example, Patient A was a 51 year old man living in Maryland who had Medicare

coverage, but no secondary health insurance policy. On August 21, 2012, an Arriva representative first called Patient A and then in September 2012 shipped him a new glucometer, two boxes of diabetic testing strips, one box of lancets, lancet devices, control solution, and a free cookbook. On September 11, 2012, Arriva billed Medicare for all of these supplies except for the cookbook for the dates of service from September 6, 2012 through December 5, 2012.

337. On September 19, 2012, Medicare paid Arriva $141.24 for the above-billed items, representing a breakdown of $57.42 for the glucometer, $54.71 for strips, $13.37 for the lancet device, $8.02 for lancets, and $7.72 for control solution. Arriva never sent Patient A an invoice for his required copayment of $35.31; and, Patient A never paid any of this copayment. Instead, Arriva wrote off all of Patient A's copayment obligation using the code 02 for "small balance write-off."

338. Arriva retained Patient A as a customer and continued shipping him diabetic testing supplies approximately every three months for several years. Arriva did not send a single invoice to Patient A until September 2014 – two years after Arriva began supplying him diabetic testing supplies. But even that invoice failed to bill Patient A for any of the supplies from the September 2012 date of service. Arriva never collected any copayments from Patient A during that entire period and wrote off all of his copayment obligations. Medicare paid Arriva approximately $860 for the diabetic testing supplies that it sent Patient A between September 2012 and October 2014, which Arriva knew was not reimbursable due to having been tainted by kickbacks in the form of waived copayments.

339. Patient B was a 74 year old woman living in Ohio who had Medicare as her primary health insurance and AARP Medicare RX Preferred as a secondary health insurance policy. On December 23, 2011, an Arriva representative first called Patient B and then shipped her a new

glucometer, two boxes of diabetic testing strips, one box of lancets, lancet devices, control solution, and a free cookbook. On January 3, 2012, Arriva billed Medicare for all of these supplies except the cookbook for the dates of service from December 28, 2011 through March 27, 2012. On January 5, 2012, Arriva's call notes reflect that Patient B called Arriva "wanting to know if she has to pay anything" for the supplies and that Arriva's call representative told her that her "80% will be billed to Medicare and [the] remaining 20% [copayment] should be covered by 2ND INSURANCE."

340. On February 1, 2012, Medicare paid Arriva $138.65 for the above shipment of diabetic testing supplies to Patient B, representing a breakdown of $56.07 for the glucometer, $53.42 for strips, $13.06 for the lancet device, $7.83 for lancets, and $8.27 for control solution.

341. Nearly one year later, on December 21, 2012, Arriva contacted Patient B's secondary insurer – AARP – which informed Arriva that AARP could not identify Patient B as a covered beneficiary of its policy. That same day, Arriva listed Patient B's copayment obligations as a balance transfer from the secondary insurance to Patient B into its record system. But Arriva never once billed Patient B for any of her required copayments for those items, and Patient B never paid any of these copayments. Arriva later wrote off all of Patient B's $34.67 in copayment obligations for the DME it sent her in December 2011 as "uncollectible," using Arriva's code "02" that stood for "small balance write-off."

342. Arriva retained Patient B as a customer and continued shipping her diabetic testing supplies approximately every three months for several years. But Arriva did not send a single bill to her until January 2014 – more than two years after Arriva began supplying Patient B diabetic testing supplies. But even that invoice failed to charge her for any of the diabetic testing supplies for the December 2011 date-of-service. Arriva never collected any copayments from Patient B

during that entire period and wrote off all of her copayment obligations. Medicare paid Arriva approximately $543 for the diabetic testing supplies that it sent to Patient B between December 2011 and July 2013, which Arriva knew was not reimbursable due to having been tainted by kickbacks in the form of waived copayments.

343. Patient C was a then 82 year old woman living in Indiana who had Medicare as her primary health insurance and another secondary health insurance policy. On June 20, 2013, an Arriva representative first called Patient C and then shipped her a new glucometer, four boxes of diabetic testing strips, two boxes of lancets, lancet devices, control solution, and a free cookbook. On July 22, 2013, Arriva billed Medicare for all of these supplies except the cookbook for the dates of service starting on June 26, 2013.

344. On Medicare July 31, 2013, Medicare denied Arriva's claim for reimbursement of the glucometer and used the claims adjustment code 151 to indicate that payment was denied due to the Five Year Rule. But Medicare paid Arriva $137.40 for the above shipment of the remaining diabetic testing supplies to Patient C, representing a breakdown of $99.67 for strips, $16.17 for the lancets, $13.20 for the lancet device, and $8.36 for control solution. Patient C's secondary insurance denied payment for the glucometer, but paid the remaining copayments for the other diabetic testing supplies in full. Arriva then wrote off $72.34 for the glucometer, without ever sending Patient C an invoice for the cost of the glucometer, so that Patient C effectively received a free meter from Arriva when it acquired her as a customer.

345. Arriva retained Patient C as a customer and continued shipping her diabetic testing supplies approximately every three months for several years. Medicare paid Arriva approximately $1,695 for the diabetic testing supplies that it sent to Patient C between June 2013 and April 2016, which Arriva knew was not reimbursable due to having been tainted by a kickback in the form of

a free meter.

346. Patient D was a then 65 year old Medicare beneficiary living in Ohio in March 2012. On March 27, 2012, an Arriva representative first called Patient D – whom it obtained as a new customer through its acquisition of Tennessee-based AmMed Direct – and then shipped her a new glucometer, eight boxes of diabetic testing strips, control solution, and a free cookbook. On May 16, 2012, Arriva billed Medicare for all of these supplies except for the cookbook for the dates of service from March 28, 2012 through June 27, 2012. On May 19, 2012, Medicare paid Arriva $284.70 for the supplies from that date of service, including $57.42 for the glucometer.

347. On September 20, 2012, Arriva sent Patient D the one and only invoice for her copayment of $71.18 for that date of service, which Patient D did not pay. On October 7, 2013 – just seventeen days after Arriva sent Patient D that one bill – Arriva wrote off Patient D's copayment obligations for that date of service as "uncollectable" using the code 02 for "small balance write-off."

348. Arriva retained Patient D as a customer and continued shipping her diabetic testing supplies approximately every three months for several years. But during that period, Arriva only sent Patient D two bills for her copayments – the September 2012 bill discussed above and a second bill sent on February 19, 2014 for supplies sent between September 2012 and October 2013. Approximately six months later in March 2014, Patient D filled out a financial assistance form, and Arriva wrote off all of her copayments for this later period. It is not clear whether Arriva made an individualized determination that Patient D was entitled to financial assistance. Medicare paid Arriva approximately $1,400 for the diabetic testing supplies that it sent Patient D between March 2012 and July 2013, which Arriva knew was not reimbursable due to having been tainted by kickbacks in the form of waived copayments.

349. On October 9, 2014, Arriva's call notes state that Patient D requested a heating pad and that Medicare "has not reimbursed for a heating pad in the last five years." Arriva sent her the heating pad and billed Medicare for it.

350. On October 30, 2015, Arriva billed Medicare for a second glucometer in less than five years for the date of service starting on October 8, 2015 – just three and a half years after Medicare paid Arriva for a prior glucometer for Patient D in March 2012. Medicare paid Arriva $58.14 for the October 2015 glucometer, which Arriva knew was not reimbursable due to the Five Year Rule.

V. Additional Allegations Specific to Ted Albin and Grapevine

351. Facts material to the claims against Ted Albin and Grapevine were not known to the government until within the last three years of the filing of this Complaint-in-Intervention.

352. Relator's *qui tam* complaint and amended complaint contained no allegations with respect to Albin or Grapevine.

353. The first emails that were produced by Arriva and Alere to the government in connection with the investigation that led to the filing of this Complaint-in-Intervention were produced in February 2017. Albin was not a custodian, although emails to and from him were produced. At no point were Albin or Grapevine identified by Arriva or Alere as parties with knowledge or information relevant to the United States' investigation.

354. On April 30, 2018, in Nashville, Tennessee, Albin provided testimony to government investigators pursuant to a Civil Investigative Demand ("CID").

355. For the first time during his CID testimony, Albin admitted to the government, under oath, that, in connection with his position as a reimbursement consultant for Arriva, he:

(1) created the "routine policy not to send a bill for customers who owed less than $5,"

(2) "came up with the policy" of "courtesy adjustments,"

(3) personally would "write off customer co-payments" because "I could tell someone on my team 'Yes, write this off,'"

(4) engaged in such write offs "probably every week" for typically "ten patient complaints per week" from "08 to 2011," particularly where the patient "threatened to cancel" or "when meters [were] denied,"

(5) personally engaged in "mass write-off[s] of denials by Medicare" due to violations of the Five Year Rule,

(6) personally created denial trend reports that showed that "40 percent" of Arriva's claims for glucometers were denied for violations of the Five Year Rule, and helped Arriva "reserve" for the cost of paying these kickbacks, but did not, in his role as Arriva's head of reimbursement, cease or seek to cease Arriva's practice of submitting claims for all first order glucometers,

(7) directed that Arriva engage in "soft" collections because "if I asked the entire reimbursement department to collect a balance very sternly, they would have lost patients like crazy," and

(8) was paid close to "one million per year" by Arriva in connection with his reimbursement consulting services, and thus personally profited from Arriva's kickback scheme.

356. During his CID Testimony, Albin explained that he performed his reimbursement consulting work for Arriva and Alere through Grapevine. Albin's conduct alleged herein was performed within the scope of his employment at Grapevine. Thus, Grapevine is jointly and severally liable with Albin for all of Albin's alleged conduct.

357. The United States was not otherwise aware of the conduct of Albin or Grapevine alleged herein.

VI. Arriva Submitted False Claims to Medicare for Services Purportedly Provided to Deceased Beneficiaries

358. In November 2016, CMS revoked Arriva's billing number because CMS determined, based on an audit of claims submitted to Medicare by Arriva from April 2011 to April 2016, that Arriva had billed Medicare for items that were purportedly provided to 211 beneficiaries who were deceased as of the dates-of-service for the claims.

359. Prior to that, in September 2016, CMS conducted an analysis of Arriva's Medicare

billing history through the CMS' Integrated Data Repository ("IDR").

360. The IDR contains information about providers, suppliers, beneficiaries, claims, among other information. The claims data from the IDR comes from Medicare's Common Working File and Medicare's National Claims History. The date of death for a beneficiary, which is included in the IDR data, comes from the Social Security Administration death master file.

361. CMS reviewed claims submitted by Arriva to Medicare with dates of service between April 15, 2011 and April 25, 2016.

362. CMS's IDR data analysis was limited to claims for services rendered fifteen days or more after the beneficiary's date of death.

363. The Medicare Program Integrity Manual dictates that a supplier "must" contact beneficiaries no more than 14 days prior to shipping a reorder of diabetic testing supplies to confirm that the supplies were needed. *See* MEDICARE PROGRAM INTEGRITY MANUAL, Chapter 5, § 5.2.8. The provision specifically provides:

> For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and confirm any changes/modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date.

364. Consequently, CMS's data analysis was designed to capture only those situations where the beneficiary was deceased during the period where Arriva was supposed to have contacted the beneficiary to confirm that the reorder of diabetic testing suppliers was needed.

365. CMS's data analysis determined that there were 227 claims, for 221 beneficiaries, where the date of service for the claim was 15 days or more after the death of the beneficiary.

366. In these cases, Arriva billed Medicare for diabetic supplies shipped to a deceased beneficiary and then, sometime later, billed Medicare at least one more time (and in some instances

multiple times) for additional diabetic testing supplies purportedly provided to the same deceased beneficiary.

367. CMS found that there were twelve beneficiaries for whom Arriva submitted multiple claims for dates-of-service after the beneficiaries had died.

368. For example, as shown in Exhibit A to the Complaint, Patient E was a 57 year old female Medicare beneficiary living in Michigan who died on January 18, 2013. Yet Arriva billed Medicare for sending Patient E two shipments of diabetic testing supplies well *after* her death.

369. First, Arriva shipped Patient E – and billed Medicare $560 for – a glucometer, eight boxes of strips, and four boxes of lancets with a date of service starting on May 21, 2013 – over four months after Patient E's death.

370. Then, Arriva shipped Patient E – and billed Medicare $472 for – four boxes of lancets, calibrator solution, and eight boxes of strips with a date of service starting on August 21, 2013 – more than seven months after her death.

371. Additional examples of Arriva submitting claims for items purportedly provided to deceased beneficiaries include the following:

372. Patient F was a 77 year old female living in Kentucky who died on June 5, 2014. Arriva ran a Medicare eligibility check for Patient F on July 1, 2014, which showed that she was deceased. Notwithstanding this, on August 20, 2014, Arriva shipped Patient F – and billed Medicare $357 for – six boxes of strips, three boxes of lancets, and one control solution. This was two and half months after Patient F died in June 2014, and seven weeks after Arriva knew that she was deceased.

373. Medicare denied the above claims for supplies for Patients E and F. But Arriva never should have billed Medicare for these supplies given that they were not reimbursable.

374. On April 25, 2017, an administrative law judge (ALJ), in a detailed thirty-page opinion, affirmed CMS's revocation of Arriva's Medicare billing privileges. *See Arriva Medical LLC v. Centers for Medicare & Medicaid Servs.*, Doc. No. C-17-233, Decision No. CR4834, 2017 WL 1652519 (H.H.S. Apr. 25, 2017).

375. The Medicare revocation was an administrative matter, subject to the applicable administrative law. The ALJ's review of the revocation of Arriva from the Medicare program, and the subsequent review by the Departmental Appeals Board of the U.S. Department of Health and Human Services, were not based upon administrative findings of fraudulent intent or otherwise knowing conduct. They were based on the administrative standard set forth in the Medicare regulations at 42 C.F.R. 424.535(a)(8)(i). The regulatory standard applicable to a Medicare revocation under 42 C.F.R. 424.535(a)(8)(i) does not entail an intent or knowledge component.

376. However, in support of its decision, the ALJ found that Arriva "admitted" that on at least nine occasions it had submitted claims to Medicare for supplies purportedly provided to a beneficiary where Arriva "knew" that the beneficiary was deceased. According to the ALJ, in these nine instances, Arriva "was able to successfully access [a Medicare database that indicated that each of the nine beneficiaries was deceased] in advance of contacting the beneficiaries to obtain approval for a refill of their diabetic supplies, and Petitioner[1] knew that all of these nine beneficiaries were deceased before seeking approval for refills and shipping the supplies."

377. Specifically, the AJL found that:

- "Petitioner admitted that there were a number of instances in which [a Medicare database] reported a beneficiary's death, but Petitioner shipped diabetic supplies anyway."
- "Petitioner has conceded that on nine occasions it knew a Medicare beneficiary was

[1] "Petitioner" refers to Arriva.

deceased yet nonetheless obtained authorization for a reorder of diabetes supplies, shipped the beneficiary supplies, and then billed Medicare for those supplies. This practice occurred over the course of nearly a year, and each time Petitioner billed Medicare, its claims were promptly denied because the beneficiary was deceased at the time of service. Therefore, Petitioner was informed, on a recurring basis, that it had been shipping supplies to beneficiaries that it knew were deceased."

- "Petitioner *admitted* that it had knowingly billed for items provided to deceased beneficiaries on nine of those occasions. The undisputed evidence shows that Petitioner admitted that it 'mistakenly continued to process the order' for each of the nine instances in which an eligibility check conducted prior to the date of reorder of supplies revealed that the beneficiary was deceased. Further, while Petitioner argued that these 'isolated instances' occurred over a 'short period of time during a systems change,' the undisputed evidence shows that these nine instances occurred over the course of nearly a year." (emphasis in original)

- "Petitioner has admitted to billing Medicare on at least nine occasions for providing supplies to beneficiaries it knew were deceased. Petitioner's own admissions, and the records Petitioner submitted supporting those admissions, constitute the undisputed material facts."

- "Petitioner has admitted it submitted claims for services that could not have been performed."

378. The ALJ further identified the specific instances where Arriva admitted that it had billed Medicare for services to a beneficiary on a date when it knew that the beneficiary was deceased.

379. Specifically, the ALJ found that "Petitioner admitted the following:

- It billed for services to Beatrice on September 17, 2013, even though it had learned on September 1, 2013, that she was deceased;

- It billed for services to James on October 4, 2013, even though it had learned on September 1, 2013, that James was deceased;

- It billed for services to Marin on April 23, 2014, even though it had learned on April 1, 2014, that Marin was deceased;

- It billed for services to Douglas on April 30, 2014, even though it had learned on April 2, 2014, that Douglas was deceased;

- It billed for services to Richard on May 27, 2014, even though it had learned on May 1, 2014, that Richard was deceased.

- It billed for services to Elmer on June 20, 2014, even though it had learned on June 2, 2014, that Elmer was deceased;
- It billed for services to Marjorie on July 23, 2014, even though it had learned on July 2, 2014, that Marjorie was deceased;
- It billed for services to Clarence on August 19, 2014, and even though it had learned on August 1, 2014, that Clarence was deceased;
- It billed for services to Mae on August 20, 2014, even though it had learned on July 1, 2014, that Mae was deceased."

380. On May 24, 2019, in a decision dated March 28, 2019, the Departmental Appeals Board, Appellate Division of the Department of Health and Human Services unanimously affirmed the ALJ's decision and the revocation of Arriva's Medicare billing number. *See In re Arriva Medical, LLC*, Dkt. No. A-17-82, Dec. No. 2934, Departmental Appeals Board, Appellate Division (Mar. 2019). The Appeals Board first found that "Arriva does not dispute the ALJ's central finding . . . that Arriva billed Medicare on nine occasions for supplies furnished after the beneficiary had died." *Id.*at 10; *see id*. at 11 ("Arriva does not dispute the ALJ's finding as to improper billing on at least nine occasions."). It then held that given that "Arriva repeatedly billed Medicare for supplies furnished to beneficiaries after a Medicare eligibility check indicated that the beneficiaries were deceased . . . the billing errors were not merely isolated or accidental occurrences, but rather a pattern of improper billing." *Id.* at 12; *see id*. at 14 ("Arriva continued to process orders and bill Medicare when it had information indicating that the supplies could not be used by the intended recipients").

381. In addition to the above, Arriva's knowledge of the falsity of its claims is aptly demonstrated by its submission of claims for items that were purportedly provided to deceased beneficiaries (but, which, could not have been because the beneficiaries were not alive) after the 14 day notice period.

382. This could only have occurred because Arriva either (1) did not follow applicable

Medicare directives that Arriva contact beneficiaries within 14 days of shipping refills, or (2) knew that the beneficiaries were deceased and shipped the refill orders and submitted the resulting claims to Medicare notwithstanding this knowledge.

383. Either way, at the very minimum, Arriva acted, at least, recklessly in submitting the false claims. In fact, as the ALJ found, Arriva acted intentionally in at least nine instances. Thus, Arriva knew that the claims were false.

384. Whether the beneficiary was alive on the dates-of-service is material to whether CMS will pay a claim submitted to Medicare. Beyond the obvious fact that (i) a deceased beneficiary is not entitled to Medicare coverage, and (ii) services identified in a claim could not possibly have been provided to a beneficiary who was not alive on the date-of-service, Medicare rules specifically authorize the revocation of providers who bill Medicare for services that were purportedly provided to deceased beneficiaries. *See* 42 C.F.R. § 424.535 (allowing revocation where: "[t]he provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service . . . [such as] where the beneficiary is deceased").

385. Additionally, CMS revoked Arriva's billing number because of Arriva's submission of claims for deceased beneficiaries (which has been affirmed through multiple administrative appeals), further establishing the materiality of this issue to CMS's payment decision.

386. Thus, a reasonable person would know that whether the beneficiary was deceased on the date-of-service for a claim is material to the United States' payment decision.

VII. Damages

387. The United States' damages include tens of millions of dollars (or more) that were

paid by Medicare to Arriva for claims that were tainted by Defendants' kickback schemes. The United States seeks damages for claims tainted by kickbacks in violation of the AKS that were submitted to Medicare from April 2010 through at least November 2016 when Arriva's Medicare billing number was revoked.

388. Additionally, the United States' damages include the amounts that Medicare paid for those claims that were submitted in violation of the Five Year Rule and for which the beneficiary was deceased more than fourteen days before the dates-of-service in the claim. The United States seeks damages for all non-AKS-based claims from Arriva's opening in 2009 until at least November 2016 when Arriva's billing number was revoked.

389. To the extent that Arriva submitted and Medicare paid for false claims after November 2016, the United States seeks damages for those claims as well.

390. The United States is entitled to an award of treble these damages, as well as statutory penalties. *See* 31 U.S.C. §§ 3729(a)(1). The United States is also entitled to its costs prosecuting this litigation against Defendants. *See* 31 U.S.C. § 3729(a)(3).

CAUSES OF ACTION

COUNT I
(Presentment of False Claims to Medicare; 31 U.S.C. § 3729(a)(1)(A))

391. The United States incorporates and re-alleges all the allegations contained in this Complaint-in-Intervention into this paragraph.

392. Defendants knowingly submitted or caused to be submitted claims for payment or approval to the United States for diabetic testing supplies or other items that were false as the result of the payment of kickbacks to Medicare beneficiaries in the form of (i) "free" or "no cost" glucometers, and/or (ii) the routine waiver of beneficiary copayment obligations, which was material to the United States' decision to pay those claims.

393. Defendants knowingly submitted or caused to be submitted claims for payment or approval to the United States for glucometers that were false because the Medicare beneficiaries had received glucometers paid for by Medicare within the past five years and thus, pursuant to 42 U.S.C. § 1395m(a)(7)(C)(ii) and 42 C.F.R. § 414.210(f)(1), were not entitled to receive new glucometers paid for by Medicare, which was material to the United States' decision to pay those claims.

394. Defendants knowingly submitted or caused to be submitted claims for payment or approval to the United States for diabetic testing supplies and other items that were materially false because the claims (1) falsely certified that the claims were "accurate, complete, and truthful," (2) falsely certified that "the claim[s], whether submitted by me or on my behalf by a designated billing company, complies with all applicable Medicare and/or Medicaid law, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute," (3) falsely certified that Medicare was "provided . . . [with] sufficient information required to allow the government to make an informed eligibility and payment decision," (4) falsely stated that the beneficiary was entitled to have Medicare pay for a new or replacement glucometer for the beneficiary, (5) falsely stated the actual charge for items for which payment was sought from Medicare because the charge did not take into account that Arriva waived the beneficiary's copayment obligation, (6) concealed and/or failed to disclose that the claims were tainted by unlawful kickbacks in violation of 42 U.S.C. §1320a-7b, and (7) concealed and/or failed to disclose that beneficiaries were not entitled to have Medicare pay for a new or replacement glucometer pursuant to 42 U.S.C. § 1395m(a)(7)(C)(ii).

395. Arriva knowingly submitted or caused to be submitted claims for payment or approval to the United States for diabetic testing supplies and other items that were false because

the Medicare beneficiaries to whom the items were purportedly furnished were deceased on the dates-of-services indicated in the claims, which was material to the United States' decision to pay those claims.

396. Arriva knowingly submitted or caused to be submitted claims for payment or approval to the United States for diabetic testing supplies and other items that were false because the claims (1) falsely stated that items or services were provided to persons, when in fact they were deceased on the indicated dates-of-services, and (2) concealed and/or failed to disclose that beneficiaries were deceased on the indicated dates-of-service, which were material to the United States' decision to pay those claims.

397. The United States has suffered damages because of Defendants' alleged conduct.

398. The United States is entitled to an award of treble its damages, plus statutory penalties pursuant to 31 U.S.C. §§ 3729(a)(1).

399. The United States is also entitled to its costs prosecuting this litigation against Defendants, pursuant to 31 U.S.C. § 3729(a)(3).

COUNT II
(False Record or Statement to Medicare; 31 U.S.C. § 3729(a)(1)(B))

400. The United States incorporates and re-alleges all the allegations contained in this Complaint-in-Intervention into this paragraph.

401. Defendants knowingly made, used, or caused to be made or used, a false record or false statement that was material to claims for payment or approval to the United States for diabetic testing supplies or other items.

402. Claims submitted or caused to be submitted to the United States by Defendants (1) falsely certified that the claims were "accurate, complete, and truthful," (2) falsely certified that "the claim[s], whether submitted by me or on my behalf by a designated billing company, complies

with all applicable Medicare and/or Medicaid law, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute," (3) falsely certified that Medicare was "provided . . . [with] sufficient information required to allow the government to make an informed eligibility and payment decision," (4) falsely stated that the beneficiary was entitled to have Medicare pay for a new or replacement glucometer for the beneficiary, (5) falsely stated the actual charge for items for which payment was sought from Medicare because the charge did not take into account that Arriva waived the beneficiary's copayment obligation, (6) concealed and/or failed to disclose that the claims were tainted by unlawful kickbacks in violation of 42 U.S.C. §1320a-7b, and (7) concealed and/or failed to disclose that beneficiaries were not entitled to have Medicare pay for a new or replacement glucometer pursuant to 42 U.S.C. § 1395m(a)(7)(C)(ii).

403. Claims submitted or caused to be submitted to the United States by Arriva (1) falsely stated that items or services were provided to persons, when in fact they were deceased on the indicated dates-of-services, and (2) concealed and/or failed to disclose that beneficiaries were deceased on the indicated dates-of-service.

404. The United States has suffered damages because of Defendants' alleged conduct.

405. The United States is entitled to an award of treble its damages, plus statutory penalties pursuant to 31 U.S.C. §§ 3729(a)(1).

406. The United States is also entitled to its costs prosecuting this litigation against Defendants, pursuant to 31 U.S.C. § 3729(a)(3).

COUNT III
(Conspiracy; 31 U.S.C. § 3729(a)(1)(C))

407. The United States incorporates and re-alleges all the allegations contained in this Complaint-in-Intervention into this paragraph.

408. Defendants and their co-conspirators knowingly conspired to present or cause to be presented false or fraudulent claims for payment or approval to the United States for diabetic testing supplies or other items.

409. Defendants and their co-conspirators knowingly conspired to make, use, or cause to be made or used false records or false statements that were material to claims for payment or approval to the United States for diabetic testing supplies or other items.

410. The United States has suffered damages because of Defendants' alleged conduct.

411. The United States is entitled to an award of treble its damages, plus statutory penalties pursuant to 31 U.S.C. §§ 3729(a)(1).

412. The United States is also entitled to its costs prosecuting this litigation against Defendants, pursuant to 31 U.S.C. § 3729(a)(3).

COUNT IV
(Unjust Enrichment)

413. The United States incorporates and re-alleges all the allegations contained in this Complaint-in-Intervention into this paragraph.

414. This is a claim for the recovery of monies by which Defendants have been unjustly enriched.

415. By obtaining government funds to which they were not entitled, Defendants were unjustly enriched, and are liable to account and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the United States.

COUNT V
(Payment by Mistake)

416. The United States incorporates and re-alleges all the allegations contained in this Complaint-in-Intervention into this paragraph.

417. This is a claim against Arriva for the recovery of monies paid by the United States to Arriva as a result of a mistaken understandings of facts.

418. The false claims which Arriva submitted to the United States' agents were paid by the United States based upon mistaken or erroneous understandings of material fact.

419. The United States, acting in reasonable reliance on the truthfulness of the claims and the truthfulness of Arriva's certifications and representations, paid Arriva certain sums of money to which it was not entitled, and Arriva is thus liable to account and pay such amounts, which are to be determined at trial, to the United States.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Defendants, jointly and severally, for Counts I through IV, and against Arriva for Count V as follows:

- On the First, Second, and Third Counts under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are permitted by law, as well as its costs pursuing this action, together with all such further relief as may be just and proper.

- On the Fourth Count for unjust enrichment, for the amounts by which Defendants were unjustly enriched, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

- On the Fifth Count for payment by mistake, for the amounts the United States paid by mistake, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

The United States demands a trial by jury.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing is being served, by use of the Court's electronic case management system, on August 1, 2019, to the following:

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s/ Ellen Bowden McIntyre
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